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Ingredients

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Drug makers in bind due to stand on methylcobalamin

OUR BUREAU, MUMBAI

Drug makers are in a bind due to Food Safety and Standards Authority of India (FSSAI)'s dubious stand on approval of methylcobalamin, commonly known as vitamin B12.

On the one hand, Bhaskar Narayan, advisor (science & standards), FSSAI has reiterated that methylcobalamin should not be used by manufacturers as it is not listed under 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.

On the other hand, thousands of FSSAI approved brands with methylcobalamin (far beyond the recommended dietary value limits) are already available in the markets.

Few of them are Health Aid Vitamin B12 (methylcobalamin) 1500 mcg, Nature Made Vitamin B12-1000 mcg, B-12 dots by Twinlab-500 mcg, Jarrow Formulas, Methyl B-12-1000 mcg, Nature's Bounty Vitamin B-12 1000 mcg, Source naturals methylcobalamin Vitamin B12-5000 mcg, solgar sublingual methylcobalamin supplement-1000 mcg, Cofactor CD3 plus tablet-1500 mcg, nocoob methylcobalamin 1500mcg, unived methylcobal-

amin 1500mcg, Bhumiya Lifesciences vitamin B12 1500 mcg, bluebonnet liquid methylcobalamin - vitamin B12 1000 mcg, EZ Melts B12 as methylcobalamin, 2,500 mcg and Garden of Life Vitamin Code vitamin B12-1000 mcg etc.

FSSAI had banned methylcobalamin through the gazette passed in 2016. The product was later approved by the scientific committee of FSSAI in December 2019 based on scientific evidence of its safe use but the amended gazette has not been issued in this regard so far.

Methylcobalamin is an essential nutrient to regulate certain vital bodily functions like cell multiplication, blood formation, and protein synthesis. Most of the manufacturers are continuously manufacturing the said product which proves the inefficiency of FSSAI.

When asked about easy availability of methylcobalamin in absence of FSSAI's gazette notification on removal of ban on the product, Bhaskar Narayan clarified that methylcobalamin can be used with prior approval by the food authority.

The easy availability of methylcobalamin far beyond the recommended dietary value (RDA) has led the experts in a dilemma to conclude whether methylcobalamin is approved or not and if the RDA is applicable to methylcobalamin or not. Considering methylcobalamin is

banned, how many brands of methylcobalamin are available in the market? And if considering methylcobalamin is not banned the question arises, why approval status is not mentioned in the gazette.

On January 7, 2020, FSSAI had issued a notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin. Vitamin B12 is found in many foods, such as meat, poultry, seafood, eggs, dairy products and fortified cereals. Most of them are classified as non-vegetarian food whereas the majority of the Indian public is vegetarian. In addition to this, various medications, namely metformin, proton-pump inhibitors, such as prilosec or H2 receptor antagonists such as pepcid interfere with B12 absorption. Therefore, such people need more methylcobalamin, said Dr Sanjay Agrawal, pharmaceutical consultant.

As per Section 22 of FSS Act, 2006 and nutraceutical regulations, health supplements or nutraceuticals shall contain minerals or vitamins only in amounts not exceeding the RDA for Indians. Hence, as per the said Act and Regulations, these products can contain vitamins or minerals only up

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Regulator issues draft prescribing Basmati rice stds

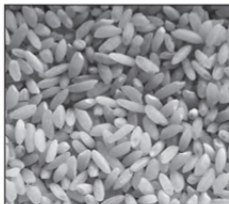
OUR BUREAU, NEW DELHI

THE Indian food authority, FSSAI, has issued a draft prescribing 'Basmati Rice Standards' and sought stakeholders comments on the same. Called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2021, it includes standards for 'Basmati Rice' in regulation number 2.4 that covers cereals and cereal products.

According to the draft, 'Basmati Rice shall be mature kernels of the varieties of *Oryza sativa* L. notified under the Seeds Act, 1966 (54 of 1966) as Basmati, which shall possess natural fragrance, characteristic of Basmati rice both in raw and cooked forms and shall be free from artificial colouring, polishing agents and artificial fragrances.'

The types of Basmati Rice include Brown Basmati, Milled Basmati, Parboiled Brown (de-husked), Milled Parboiled and Blended Basmati Rice (mixture of milled Basmati rice -80% with other long grain non-Basmati rice).

The draft says that the Average Length (mm) of Basmati rice should be 7.0 and above for brown rice, and 6.61 and above for milled variety. The average cooked rice length (mm) should be 12.0 while the average length -

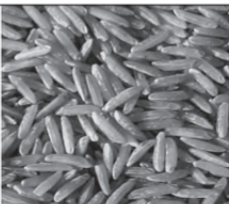


breadth ratio should be 3.5mm.

The other standards include, moisture percent by mass, not more than 14%, other varieties of non-Basmati rice (per cent by mass with Basmati rice), not more than 5.0%, damaged discoloured grains (per cent by mass), not more than 1%, alkali spreading value (ASV) 4.0-7.0, and uric acid (mg per kg), not more than 100mg.

Further, the confirmation for Basmati Rice variety shall be done by Polymerase Chain Reaction (PCR) test, if required.

Also, every package of Blended Basmati Rice containing Milled Basmati Rice and other extra



long grain rice shall carry the label, - 'BLENDED BASMATI RICE contains Milled Basmati Rice..... per cent'. Other extra long grain non-Basmati rice per cent'. Besides, the type of broken rice, such as Tibar, Dubar, Mogra shall be prominently mentioned on the label.

The length prescribed by the FSSAI for broken Basmati rice includes: Basmati Rice Tibar (>6.5 mm), Basmati Rice Dubar (>6.1 mm), Basmati Rice Mini Dubar (>5.25 mm), Basmati Rice Mogra (>4.4mm) and Basmati Rice Mini Mogra (>3.8 mm). Rest of the parameters for long grain Basmati rice will be applicable on the broken Basmati rice as well.

○

FSSAI amends organic food norms; exempts aggregators from compliance

OUR BUREAU, NEW DELHI

THE Food Authority has amended the Organic Food Regulations of 2017 to include provisions that aggregators or intermediaries shall be exempted from complying with the applicable provisions of the 'organic' food certification system.

The amendment regulations were notified as the first amendment regulations for organic food standards to include a sub regulations 3 under regulation 4 (applicability of systems), which reads, "Aggregators or Intermediaries who collect organic food from small original producer or producer organisation and sell it to the end consumer directly, are exempted from the provisions of the systems referred in sub-regulation (1) and they shall maintain records of traceability and comply with any of the provisions of the systems mentioned in sub-regulation (1) and organic food shall not carry Food Safety and Standard Authority of India's organic logo."

The sub-regulation 1 says that the or-

ganic food offered or promoted for sale shall also comply with all the applicable provisions of one of the following systems, namely: - (i) National Programme for Organic Production (NPOP); (ii) Participatory Guarantee System for India (PGS-India) and (iii) Any other system or standards as may be notified by the Food Authority from time to time.

Also for labelling provisions under Regulation 5 of the Organic Food Regulations, the amendment notification added another provision 5 (3) which says, "In-conversion products under PGS-India may be labelled as 'PGS-Green' and may also be labelled as "In-conversion to organic" and the conversion products under NPOP may be labelled as "In-conversion to organic" and shall mention the year of conversion and such in-conversion products shall not carry Food Safety and Standard Authority of India's organic logo."

Under PGS and NPOP separate logos were mandated for in-conversion farms (traditional farms that are in process of getting converted into organic farms). □

Under the jurisdiction of DCGI

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who wants to produce, import, market or sell such products shall comply with the aforementioned regulations.

"The drug authorities have recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available since long as patients take methylcobalamin based on the requirement," argues (pharma consultant Dr Agrawal) who has been advocating the case of methylcobalamin RDA value with FSSAI for the benefit of mental health and boosting immunity since a long time.

"The issue has been festering due to missing exact information on tolerable upper limit (TUL) of vitamin B12 (methylcobalamin to be specific) from the public domain.

No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals. Methylcobalamin has a history of safe long-term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Additionally, we had received a letter in December 2019 from FSSAI about methylcobalamin approved RDA value for neurological disorders by the technical committee but industry is yet to see the notification on the same," added Dr Agrawal.

He stressed the need to bring regulation of nutraceuticals under the jurisdiction of DCGI who are well equipped to regulate these products. □

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