

## Food or drug? Government to take a call soon

*Regulatory framework may be tweaked; move aims to determine the category of a product. Given the confusing proliferation of products, the government is looking to arrive at an answer by changing the regulatory framework. Most companies prefer to p...*

By [Teena Thacker](#), ET Bureau | Dec 13, 2019,

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NEW DELHI: Is a multivitamin preparation a drug or just plain old food? And what about pick-me-ups like Revital or supplements like Ferradol? Given the confusing proliferation of products, the government is looking to arrive at an answer by changing the regulatory framework.

It appears the solution will be broadly along these lines: If the ingredients of a particular product are below that determined as the daily dosage, or 1RDA (Recommended Dietary Allowance), then it will be deemed 'food' and regulated by the Food Safety and Standards Act (FSSA), according to people with knowledge of the matter and documents

that ET has seen. Anything above that will be a 'drug' and regulated under the Drugs and Cosmetics (D&C) Act. 1RDA is defined as the level of nutrients to be consumed daily to meet all the requirements of a healthy individual.

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At a recent meeting between the Drug Controller General of India (DCGI) and the FSSAI, which administers the FSSA, it was decided that multivitamin preparations containing vitamins in a strength lower than 1RDA would be excluded from the D&C Act. The Act will be amended so that vitamins and minerals below 1RDA for prophylactic purpose are deleted from Schedule V.

## Pop This!

### THE AMBIGUITY

#### It stems from multivitamin

preparations being covered by both D&C Act and by FSSA

### THE LIKELY SOLUTION

If ingredients of a particular product are below that determined as daily dosage, or 1RDA\*, it will be deemed 'food'

It will be regulated under FSSA

Anything above that will be a 'drug'

It will be regulated under Drugs and Cosmetics (D&C) Act

\* Recommended Dietary Allowance

"Prophylactic levels of vitamins and minerals equal to or less than 1 RDA as specified by ICMR, may be regulated under FSSA and its rules," FSSAI told the DCGI in a November 21 letter, asking it to make the necessary amendments in the D&C Act.

Most companies prefer to position their products as health supplements under the FSSA to avoid the more onerous D&C Act regime, which could also invite price controls. The ambiguity stems from multivitamin preparations being covered by both the D&C Act and by the FSSA. Taking advantage of this overlap, companies had started seeking approval of the Food Safety and Standards Authority of India (FSSAI) to circumvent price controls and tighter regulation.

"There is an apparent regulatory overlap of FSSA and D&C Act since multivitamin composition of certain products are, in fact, used for both prevention of diseases as well as providing health benefits," said a senior government official on condition of anonymity.

For example, Abbott's product Limcee Plus, which was approved by FSSAI in January 2018 in the health supplement category, costs Rs 60 for a strip of 15 tablets. On the other hand, its chewable vitamin tablet Limcee, on the national list of essential medicines since 2013, costs Rs 14 for a strip of 15 tablets. The company says Limcee Plus contains amino acids and thus doesn't just target patients who suffer from [vitamin C](#) deficiency.

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