# FLAVORED WATER INDUSTRY IN A FIX OVER REGULATION



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**Flavored water industry in a fix over regulation**

The flavored water industry in India is facing problems under the PFAR which regulates the packaging and manufacture of packaged drinking water. A Chennai based foundation named International Herbal Water Foundation ("the Foundation") has written to the FSSAI highlighting the grievances of the industry and the specific problems faced by the industry under the PFAR due to lack of appropriate standards. Under the PFAR, flavored packaged drinking water is misunderstood by the implementing agencies as packaged drinking water which is then brought under the purview of Rule 49(28) of the PFAR which prohibits sale of such a product without a BIS certification mark. Further, packaged drinking water is defined under the PFAR as water to which no additives are added and which undergoes some special process for purification. Due to this, since there are additives in flavored water, many implementing agencies have shut down and sealed plants which has caused a substantial amount of fiscal losses to companies in this industry.

**PSA view** – The Foundation has raised a plea with the FSSAI that flavored water does not fall within the definition of Packaged Drinking Water as mentioned under the PFAR, and alleges that it should fall under the purview of proprietary foods. Proprietary foods are provided for under rule 37 and are those which have not been specifically covered under the FPAR. Though a simple solution, the FSSAI needs to assess if it should simply exclude the application of the BIS certification requirement for flavored drinking water as it still is packaged drinking water with some additive for flavor. In this light, it will be prudent to come up with a separate standard for flavored water instead of excluding the application of Rule 49 and the mandatory requirement of BIS certification.

**Rules to curb shifting of ingredients from drugs to food supplements**

The FSSAI has been asked by the health ministry to frame rules under Section 22 of the Food Safety and Standards Act in consultation with the National Pharmaceutical Pricing Authority ("NPPA"), to check the practice of pharma companies changing ingredients of drugs to dodge price control mechanism. The drug companies have been found changing some drug ingredients to convert the formulations into food and nutrition supplements in a bid to circumvent the Drug Price Control Order, 1995. NPPA had reported the issue to the health ministry and had also urged the Drug Controller General of India to take action by bringing in necessary amendment to the Drugs and Cosmetics Rules to stop companies from replacing drug ingredients with food ingredients.

**PSA view** – The NPPA has relied upon the instances of Evion 400mg, Revital, Recharge Plus, and Soft Z gold, which allegedly shifted the production of medicines that are under price control to food and nutrition supplements manufactured under Prevention of Food Adulteration Act, 1954 in order to circumvent the control mechanism. Strict monitoring of price control by NPPA is essential for the public interest. The companies are also required to adhere to the pricing, packaging and labeling laws to avoid unnecessary hassles. Dietary supplements have been made a special class of food under the Food Safety and Standards Act, 2006. As the Food Safety and Standards Rules are yet to be framed, the present law falls short of enforceability. But with this Act the trouble of lack of regulation and clear-cut guidelines for manufacturers would be sorted out.

**Task force to develop software for drug manufacturing & tracking system**

The health ministry has constituted a task force to find a software that could be used for tracking the drugs right from the manufacturers to the retailers to check the menace of counterfeiting of drugs in India. Upon the submission of the report by this task force, the health ministry will streamline the steps to enforce the recommendations. Thereupon, all the manufacturers will have to adopt the new software and the state drug authorities will be liable to keep a tab on the companies and to check whether it is implemented effectively.

**PSA view** – The software for drug manufacturing tracking system will help in tracking the medicines and control the issue of spurious drugs in the country. This will definitely ensure that all the drugs that are dispatched from the manufacturers remains traceable so as to ensure that they are not counterfeited till they reach the retailers.

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