

‘Claims regulations are in the final stage and will be announced in a few weeks’, says Pawan Kumar Agarwal

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September 2, 2018

Pawan Kumar Agarwal is the chief executive officer of food regulator Food Safety and Standards Authority of India (FSSAI), which brought out new regulations in 2016, covering nutraceuticals, foods for special dietary and medical use, etc. The enforcement of the regulations commenced from January this year. In an interview with Smitha Verma, he talks about the role of the food regulator and the responsibilities of manufacturers. Edited excerpts:

Many new products under the nutraceuticals category keep appearing on store shelves. What kind of checks and balances does the FSSAI have in place for these products?

Products in the category of health supplements and nutraceuticals are required to comply with the rules and regulations issued by the FSSAI. Food business operators are required to set up a Food Safety Management System (FSMS) to ensure that their products are safe. The regulations list ingredients, including food additives that are permitted. Furthermore, state authorities inspect all products.

Manufacturers of several supplements make fraudulent claims like 'cure for infertility/diabetes', etc...

The problem arises when you are taking supplements where there is no need because of misinformation. Since there is no issue of lack of safety here, we can't book on that note. But now, the main issue we are working on, which needs immediate attention, is related to claims made by manufacturers regarding their products. The claims regulations are in the final stage and will be announced in a few weeks' time.

So if a manufacturer introduces any new ingredient in a supplement, they have to prove, through testing, how the new ingredient will fulfill the claims they are making. They have to substantiate and produce evidence of why they are making the claim. If they fail to do so, they will be penalised.

Do consumers have enough awareness about nutraceuticals? Or are they popping these pills thinking there are no side-effects?

Health supplements and nutraceuticals is an emerging food sector in India and the FSSAI's regulation for the sector is the first of its kind in the country. Being a new category compared to other foods, awareness-building measures are certainly required to educate consumers. The industry body CII has partnered with the International Association of Dietary/Food Supplement Association (IADSA) to set up the Resource Centre for Health Supplements and Nutraceuticals (ReCHaN), which is developing FSMS guidance documents, manuals and interactive sessions on scientific aspects. ReCHaN would also be contributing towards educating consumers... they are going to come back to us in a few weeks' time... We also have to educate food inspectors as to how to carry out inspections at factories. The training is going on.

There seems to be some confusion about food supplements and Ayurvedic/herbal medicines...

A health supplement is a hybrid between a food and a drug. Globally, too, there is a bit of confusion around it. There is an area of overlap between us and the Drugs Control Department, which we are trying to resolve. When we

notified our regulations in 2016, the ministry of AYUSH felt that we were encroaching upon their territory and a series of meetings were held where this issue was resolved.

There are many Ayurvedic plants that are used in supplements. They have their Ayurvedic name, but here we call them 'botanicals'. When it is categorised as 'food', the rigour with which manufacturers have to carry out clinical trials reduces significantly. If you classify something as food, the export also becomes easy. Getting recognition for Indian Ayurvedic medicines across the world is also a challenge. It depends on the manufacturer if he declares the product as a food supplement or drug and, accordingly, the regulator gets decided.