

FSSAI to frame regulations for product approval

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To overcome the recent setback from various courts relating to the advisory issued for product approval, the Food Safety and Standards Authority of India (“**FSSAI**”) is proposing to issue new regulation to simplify the product approval regime. For this purpose, FSSAI has invited proposals from law firms/lawyers to provide legal assistance to FSSAI to formulate the new regulation.

The product approval scheme^[1] was launched by Food Safety and Standards Authority of India (“**FSSAI**”) through its advisory dated 11 May 2013. It stipulates that the food products for which the standards are not specified under the Food Safety and Standards Act, 2006 (hereinafter referred to as the “FSS Act”), and other Rules and Regulations made under it, will be granted product approval subject to its procedure.^[2]

Vital Nutraceuticals, an exporter, supplier and manufacturer of nutraceuticals, functional foods and dietary food supplements, and the Indian Drug Manufacturers' Association decided to challenge this scheme before the Bombay High Court, and prayed for quashing the product approval scheme.

The issue was whether the advisories issued by FSSAI, and in particular, the one issued on 11 May 2013, are without authority of law and whether it had the power to issue these advisories without following the due procedure laid down under Sections 92 and 93 of the FSS Act, 2006.

The Division Bench at the Bombay High Court had differing views. Justice V.M. Kanade was of the opinion that the said advisory which makes it compulsorily applicable even to existing manufacturers, is *ultra vires* the provisions of the Act and the Rules and Regulations framed thereunder.^[3] The impugned advisory, insofar as it relates to existing manufacturers who had licenses and registration prior to the present FSS Act, 2006 and Regulations of 2011 coming into force, was quashed and set aside.

However, Justice Girish S. Kulkarni disagreed with the view taken by Justice Kanade.

In view of the fact that the Division Bench of the Bombay High Court had differing views on the matter, it was referred to a third judge, Justice Ranjit More.

He upheld the view of Justice Kanade that the FSSAI has no authority to issue such advisories without approval from both the Houses of Parliament. He left it open to the FSSAI to prescribe specific standards in respect of food items which have already been recognized as proprietary foods, by issuing regulations for it. The FSSAI, which is obliged to do something by way of framing regulations, was not allowed to do the same by issuing advisories. FSSAI was mandated with the duty of issuing regulations in respect of matters covered under clauses (a)-(i) of Section 16(2) and clauses (a)-(v) of Section 92(2), and the same was not allowed to be achieved by issuing advisories, *in lieu*.

FSSAI filed a special leave petition before the Supreme Court, which dismissed their plea stating lack of grounds for its interference, and withheld its judgment pending a concrete decision of the Bombay High Court.

As a result the above judgment, the FSSAI has to withdraw the earlier advisory issued for product approval.

The earlier product approval regime has caused mayhem in the food industry due to various uncertainties caused by the advisory. The FSSAI shall ensure that the new regulations must take care of these uncertainties with definite procedure and time frame for providing approval.

[1] [http://fssai.gov.in/Portals/0/Pdf/FPAS\(11.09.14\).pdf](http://fssai.gov.in/Portals/0/Pdf/FPAS(11.09.14).pdf)

[2] [http://www.fssai.gov.in/Portals/0/Pdf/productApproval\(17-05-2013\).pdf](http://www.fssai.gov.in/Portals/0/Pdf/productApproval(17-05-2013).pdf)

[3] http://www.fssai.gov.in/Portals/0/Pdf/Court_Order_Vital.pdf