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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
+ **W.P.(C) 1251/2019**
LEPRO HERBALS PRIVATE LIMITED

..... Petitioner

Through: Mr.D.P. Singh, Ms.Sonam Gupta,
Ms.Ishita Jain, Ms.Shreya Dutt, Advs.
with Mr.Sandeep Malik & Mr.Sunil
Malik, AR of petitioner.

versus

**FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
AND ANR.**

..... Respondents

Through: Mr.John Thomas & Ms.Puspita
Basak, Advs. for R-1.
Mr.Dev. P Bhardwaj, CGSC with
Mr.Abhishek Yadav & Mr.Jatin
Teotia, Advs. for R-2.

CORAM:
HON'BLE MR. JUSTICE NAVIN CHAWLA

ORDER
% **21.01.2020**

The present petition has been filed challenging the direction dated 31.12.2018 issued by the respondent no. 1 to the extent that it directs the Food Business Operators to discontinue use of Saw Palmetto in the products covered under the Food Safety And Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food And Novel Food) Regulations, 2016 (hereinafter referred to as the 'Regulation').

It is the case of the petitioner that the Impugned Direction has been

passed for the said ingredient only on the ground that there was a lack of adequate data of safe usage of the said ingredient in India for fifteen years. The learned counsel for the petitioner, placing reliance on Clause 7(2)(v) of the Regulations, submits that in absence of a safe usage of atleast fifteen years in India, the petitioner was entitled to produce evidence of usage of thirty years in the Country of origin. He submits that in the present case, the petitioner had submitted several materials of the usage of this ingredient in the United States of America, that is the Country of origin and other parts of the world, since 1870's. He submits that these materials were ignored as the respondent did not properly consider the provision of Clause 7(2)(v) of the Regulations.

When this petition was partly heard on 16.12.2019, the learned counsel for the respondents sought time to seek instructions on whether the Regulations and specifically Clause 7(2)(v) thereof has been amended. Today he submits that though no such amendment has been carried out, a process of amending the Regulation is underway.

Be that as it may, Regulation 7(2)(v) of the Regulations as it stands today reads as under:-

"7. Nutraceuticals.-

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(2) (v) For the purposes of clause (iv), a food business operator shall apply to the Food Authority for approval which shall be accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin;"

(emphasis supplied)

A reading of the above would clearly show that for the purpose of

granting approval under Clause 7(2)(iv) of the Regulations, a Food Business Operator has to apply to the Food Authority for approval and such application should accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin.

As noted hereinabove, the case of the petitioner is that it has supplied documents showing thirty years of usage in the Country of origin. The Impugned Direction insofar as this aspect is concerned, does not show the consideration of these documents by the respondent no. 1.

Accordingly the Impugned Direction dated 31.12.2018, insofar as it relates to Saw Palmetto, is set aside directing the respondent no. 1 to reconsider the application of the petitioner for grant of approval afresh after giving due opportunity of hearing to the petitioner. In such hearing the petitioner shall be at liberty to file further material/representation before the respondent no. 1.

The petition is allowed in the above terms.

NAVIN CHAWLA, J

JANUARY 21, 2020/rv