FSSAI

FSSAI says ashwagandha leaves are not permitted in food products

FSSAI's advisory of April 16, 2026 says Schedule IV permits only ashwagandha roots and their extracts, and leaves in crude, extract or any other form are not.

THE FOOD SAFETY AND Standards Authority of India (FSSAI), Regulatory Compliance Division, issued an advisory dated April 16, 2026 under F. No. RCD-15001/11/2021-Regulatory-FSSAI. Its subject is the non-use of Ashwagandha (Withania somnifera) leaves in crude or extract or any other form in food products. It concerns 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, under which FSSAI has set standards for health supplements, nutraceuticals, food for special dietary use and food for special medical purpose. Schedule IV of those regulations lists the plants or botanicals permitted for use in such products.

KEY FACTS

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Advisory, F. No. RCD-15001/11/2021-Regulatory-FSSAI

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The advisory states: "As per Schedule IV of the aforesaid regulations, only the roots and their extracts of Ashwagandha (Withania somnifera) are permitted for use in the above-mentioned categories of products, subject to compliance with the prescribed limits." FSSAI says it has come to its notice that certain manufacturers of these products are using ashwagandha leaves and leaf extract. It clarifies that the use of ashwagandha leaves in crude or extract or any other form is not permitted under the regulations. The advisory does not reproduce the Schedule IV entry itself or state the prescribed limits.

FSSAI advises all Food Business Operators (FBOs) to ensure strict compliance and says any deviation shall attract action under the Food Safety and Standards Act, 2006 and the regulations made under it. It asks the Commissioners of Food Safety of all States and UTs and FSSAI's Regional Directors to direct the concerned Licensing Authorities and Food Safety Officers to maintain strict vigilance and ensure compliance, and says appropriate action shall be initiated against any non-compliance observed. It is addressed to all FBOs, the Commissioners of Food Safety, and FSSAI's Regional Directors and Central Licensing Authorities. It is issued with the approval of the Competent Authority and signed by Dr. Amit Sharma, Executive Director (Compliance Strategy).

The enclosed Ministry of Ayush (Drug Policy Section) letter, T-13020/4/2022-DCC-Part(2) of April 15, 2026, directs Ayush drug and product manufacturers, exporters and sellers to use only ashwagandha roots, in crude or extract or any other form, alone or as an ingredient in compound Ayush drugs and products. It strictly prohibits the leaves in any form, and tells them to comply with rule 161 of the Drugs Rules, 1945, which requires the plant parts used to be clearly mentioned on the label. It notes that in 2024 the Ministry, through a multidisciplinary expert committee, published an updated Ashwagandha safety dossier and report, which recommended that the roots be used for health benefits. It also notes that scientific studies reported possible safety concerns for the leaves due to higher concentrations of reactive withanolides, particularly Withaferin-A. Its own enclosure, a Ministry letter of October 6, 2021 (L.11011/9/2021-DCC) advising against the leaves, is not in the published file.

The advisory gives no start date, no transition period and no time to sell or use up existing stock. It does not say how products already made, labeled or on sale are to be treated, and it does not mention imported products. It sets no labeling requirement of its own: the direction to state the plant part on the label is in the Ayush letter, under the Drugs Rules, 1945, for Ayush products.

Issued by	Food Safety and Standards Authority of India (FSSAI), Regulatory Compliance Division
Document	Advisory, F. No. RCD-15001/11/2021-Regulatory-FSSAI
Dated	April 16, 2026
Applies to	Food Business Operators, including manufacturers of health supplements, nutraceuticals, food for special dietary use and food for special medical purpose
Regulations	Schedule IV of 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
Permitted	"only the roots and their extracts of Ashwagandha (Withania somnifera)", subject to the prescribed limits
Not permitted	Ashwagandha leaves in crude or extract or any other form
Enforcement	Commissioners of Food Safety of all States and UTs and Regional Directors, FSSAI, through Licensing Authorities and Food Safety Officers
Non-compliance	Action under the Food Safety and Standards Act, 2006 and the regulations made under it
Takes effect	No date stated; no transition period or stock relief
Enclosure	Ministry of Ayush letter T-13020/4/2022-DCC-Part(2), April 15, 2026: only ashwagandha roots in Ayush drugs and products; leaves strictly prohibited; plant parts used to be mentioned on the label under rule 161 of the Drugs Rules, 1945
Signed by	Dr. Amit Sharma, Executive Director (Compliance Strategy)

The advisory (PDF, 613 KB)

Source: FSSAI's own copy.

Checked against the official copy on October 28, 2026.

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Read online: indusdesk.com/fssai/insights/fssai-says-ashwagandha-leaves-are-not-permitted-in-food-products/