

F. No. RCD-15001/11/2021-Regulatory-FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006) (Regulatory
Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 16th April, 2026

Advisory

Subject: Advisory regarding non-use of Ashwagandha (*Withania somnifera*) leaves in crude or extract or any other form in food products - reg.

FSSAI has specified the standards for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose 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. Schedule IV of these regulations provides the list of plants or botanicals permitted for use in such products.

2. 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.

3. It has been brought to the notice of FSSAI that certain manufacturers of these products are using ashwagandha leaves and its extract in their products.

4. In this regard, it is clarified that the use of Ashwagandha leaves in crude or extract or any other form is not permitted under the said regulations.

5. Further, Ministry of Ayush, vide letter dated 15.04.2026 (copy enclosed), has also directed Ayush drug/product manufacturers to use only *Ashwagandha* roots and their extracts and not the leaves, in any form.

6. In view of the above, all Food Business Operators (FBOs) are hereby advised to ensure strict compliance with the aforementioned provisions. Any deviation shall attract action under the Food Safety and Standards Act, 2006 and regulations made thereunder.

7. The Commissioners of Food Safety of all States/UTs and Regional Directors, FSSAI are requested to direct the concerned Licensing Authorities and Food Safety Officers to maintain strict vigilance and ensure compliance with the above provisions. Appropriate action shall be initiated against any non-compliance observed under the Food Safety and Standards Act, 2006, and regulations made thereunder.

This issues with the approval of the Competent Authority.


(Dr. Amit Sharma) 16/04/26

Executive Director (Compliance Strategy)

Encl: As above

To:

1. All Food Business Operators

2. The Commissioner of Food Safety of all States/UTs
3. All Regional Directors, FSSAI
4. All Central Licensing Authorities, FSSAI

Copy for information to:

1. Sr. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. Secretary, Ministry of Ayush
4. SBCD, FSSAI – for disseminating information through social media
5. CITO - for uploading on the FSSAI website

T-13020/4/2022-DCC-Part(2)
Government of India
Ministry of Ayush
(Drug Policy Section)

NBCC Office Block-III(2nd Floor)
East Kidwai Nagar, New Delhi
Date: 15th April, 2026

To,

All Ayush Drugs Manufacturers/ Associations.

Subject: Mandatory use of Ashwagandha (*Withania somnifera*) roots in Ayush products -reg.

Sir/Ma'am,

Ministry of Ayush vide letter no. L.11011/9/2021-DCC dated 06.10.2021 (**Copy enclosed**) had advised Ayush Drug Manufacturers, Exporters, Sellers not to use Ashwagandha leaves either in crude or extract or any other form in Ayush drugs/ products.

2. It has been brought to the notice of Ministry of Ayush that certain Ayush manufacturers are still using Ashwagandha leaves in their products. In this regard, it is pertinent to mention that –

- i. *Ashwagandha* (*Withania somnifera*) root is widely used herb in Ayush systems.
- ii. In the year 2024, Ministry through a multidisciplinary expert committee published updated Ashwagandha safety dossier and its report, which categorically recommended that Ashwagandha roots should be used for health benefits. (Available at https://ayush.gov.in/#!/quality_standard)
- iii. Available scientific studies reported possible safety concerns for Ashwagandha leaves due to higher concentrations of reactive withanolides, particularly Withaferin-A. (Details at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787217>, <https://pubmed.ncbi.nlm.nih.gov/22973447/>)

3. Keeping in view, all Ayush drug/ product manufacturers, exporters, sellers are hereby directed to:

- i. Use only Ashwagandha roots in crude or extract or any other form in single or as an ingredient in compound Ayush drugs/products.
- ii. The use of Ashwagandha leaves, in crude, extract, or any other form, in

Ayush drugs/products is strictly prohibited.

- iii. Ensure compliance with the provisions of Rule 161 of the Drugs Rules, 1945, which require that the plant parts used in the drugs/products be clearly mentioned on the label.
4. This issues with the approval of Competent Authority.

Encl: As above.

Yours faithfully,
Digitally signed by
SHIELA TIRKEY
Date: 15-04-2026
13:48:01
(Shiela Tirkey)

Under Secretary to Government of India

Copy to:

1. All State/UT's Ayush Drug Licensing Authorities for information and further necessary action.
2. CEO, FSSAI, for information and further necessary action.