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File: ■ Ashwagandha (*Withania somnifera*, Solanaceae) ■ Safety

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RE: Regulatory Review of the Safety and Use of Ashwagandha as a Food, Medicine, and Cosmetic

Brendler T, Al-Mondhiry R, Lang L, Marles R, Tallon M, Raghu A. Ashwagandha: is it safe? Part 1: a regulatory review. [Published online December 19, 2025.] *Phytother Res*. doi: 10.1002/ptr.70151.

Ashwagandha (*Withania somnifera*, Solanaceae) root has a rich history in traditional Indian medicine. In Ayurvedic medicine, the herb is used as a rejuvenating tonic to support weight gain and vitality. It also has a history of use as an aphrodisiac. Ashwagandha is widely known for its ability to ameliorate the body's response to external stressors. However, recent safety concerns undermine its long-standing use in traditional medicine. Ashwagandha is regulated as a food supplement in the European Union (EU). Knowledge gaps in safety data and adverse event reports resulted in new recommendations by the Heads of Food Safety Agencies (HoA) working group, which may lead to a ban prohibiting the use of ashwagandha as an ingredient in food supplements. In some markets, safety concerns have already led to bans of ashwagandha. Other markets are taking a more conservative approach based on interpretation of the available data. The purpose of this regulatory review is to inform regulators, healthcare practitioners, and consumers of the regulatory status of ashwagandha in specific marketplaces in India, the EU, the United Kingdom (UK), the United States (US), Canada, and Australia. Additionally, this review provides recommendations for aligned regulatory measures.

In India, the Drugs and Cosmetics Act (Government of India; 1940) governs the use of ashwagandha. The Act defines the legal requirements for manufacturing medicines for sale under the Ayush traditional medicine systems. This includes specific provisions for quality, standards, labeling, and manufacturing. The Act also sets regulatory standards and enforcement provisions. The Food Safety and Standards Authority of India (FSSAI) provides standards for health supplements containing ashwagandha. The Pharmacopeia Commission for Indian Medicine and Homeopathy (PCIM&H) operates under the Ministry of Ayush. PCIM&H sets the standards for identity, purity, and strength of ashwagandha, which is set in the respective pharmacopeia of Ayush. The Ministry of Ayush supports World Health Organization (WHO)-compliant and quality certification programs. The Bureau of Indian Standards (BIS) is responsible for consumer product standardization. Finally, the National Pharmacovigilance Program for Ayush drugs is responsible for monitoring and reporting adverse events and misleading advertisements.

EU member states have authority over food safety and are responsible for enforcement, inspection, and control within their territory. Member states operate under EU legal frameworks set forth by the European Commission. The European Food Safety Authority (EFSA) acts as a scientific risk assessor charged with providing independent scientific advice, opinions, and studies to the European Commission, Parliament, and member states.

In 2013, the German Federal Institute of Risk Assessment (BfR) published a level A risk assessment for use of botanicals in food preparation, including the use of ashwagandha, with guidance from the European Food Safety Authority (EFSA). The BfR recommended that children, women who are pregnant or breastfeeding, and individuals with known liver disease avoid supplements containing ashwagandha.

BfR recommendations were not enacted within the EU, instead, a working group of the HoA was created in 2019. Its purpose was to advance Article 8 procedures. In June 2024, the HoA released its first report recommending that the European Commission prioritize Article 8 based on possible carcinogenic, mutagenic, or reprotoxic properties identified with ashwagandha use.

A risk assessment was conducted by the DTU Food Institute (Technical University of Denmark; DTU-Fødevareinstituttet; Lyngby, Denmark) on behalf of the Danish Food and Drug Administration in 2019. The DTU report found significant safety concerns with ashwagandha, including its use as an abortifacient, potential deleterious effects on sex and thyroid hormones, and adverse effects on immune and liver health. Additionally, the assessment identified an inhibitory effect on acetylcholinesterase. Their assessment concluded that a safe dose could not be determined. The Dutch National Institute of Public Health and the Environment (RIVM) issued a statement advising expectant mothers and consumers to avoid herbal products containing ashwagandha.

Other EU countries issued similar safety notifications. The Polish regulatory authorities limited the daily intake of powdered ashwagandha root to 3 g with a limit of ≤ 10 mg withanolides. The Swedish Food Agency announced that the DTU risk assessment would apply to Sweden; however, the municipalities were given individual discretion on implementation.

Following a risk assessment conducted by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES; 2024), an advisory was issued warning consumers with thyroid, hepatic, or cardiac pathologies or hyperandrogenism, pregnant and lactating women, persons taking sedatives, and children < 18 years avoid any supplements containing ashwagandha.

In the UK, herbal products are introduced based on classification as a food or drug, and each has its own applicable legislation. The *Herbal Aide-Memoire* compiled by the Medicines and Healthcare Products Regulatory Agency (MHRA) guides decisions on medicinal classification in the UK; however, it has no legal authority. Currently, there is no ban or other registrations granted for ashwagandha for medicinal or cosmetic use. In July 2024, the Food Standards Agency (FSA) initiated a risk assessment based on safety concerns of ashwagandha use or as an ingredient in food supplements. The assessment was finalized and the data are being analyzed by the Committee of Toxicity.

In the United States, the Food and Drug Administration (FDA) regulates herbal products based on their intended use. Ashwagandha is listed as a dietary supplement and has been independently generally recognized as safe (GRAS). The GRAS affirmation was without FDA review. However, it allows ashwagandha to be used in certain conventional

food products, dietary supplements, and cosmetics. Additionally, ashwagandha is not subject to labeling laws required by the FDA. The distinction is that ashwagandha is not promoted to prevent, cure, treat, mitigate, or diagnose diseases. In that instance, the herb would be classified as a drug and regulated by the FDA.

The [US] Federal Trade Commission (FTC) enforces truth in advertising laws. However, in the case of ashwagandha, the FTC only advises that any claims made should be based on clinical trial observations regarding extraction, composition, and formulation.

A Fact Sheet for Health Professionals prepared by the National Institutes of Health's (NIH) Office of Dietary Supplements lists ashwagandha as well tolerated for use up to three months with minimal side effects and only a few reports of adverse effects to liver function. The NIH recommends that those who are pregnant or lactating or have hormone-sensitive prostate cancer should avoid using supplements containing ashwagandha.

In Canada, the Natural Health Products (NHPs) regulations govern botanical products sold as traditional medicinal herbs in tablets, capsules, or tisanes as non-prescription drugs. Ashwagandha is listed in the NHPs ingredient database as a whole plant, extracts of roots, leaves, and flowers, and as homeopathic preparations. It is an established Ayurvedic and modern herbal medicine. Ashwagandha is listed as a medicinal ingredient in 200 NHPs with active licenses in Canada. However, Health Canada determined there was insufficient data available to approve its use as an ingredient in food supplements.

The Australian Register of Therapeutic Goods (ARTG) database lists 374 complementary medicines containing ashwagandha. "Listed" medicines do not undergo individual pre-market evaluation provided they select from a list of lower-risk ingredients and include associated warning labels based on scientific efficacy or traditional use. As such, ashwagandha is permitted in products used to manage stress, mild anxiety, energy, sleep, and hormonal or perimenopausal symptoms. The database is managed by the Therapeutic Goods Administration (TGA). In 2020, the TGA required a mandatory statement on products containing ashwagandha, warning of its abortifacient effects. In 2024, the TGA published an advisory warning related to potential hepatotoxic and gastrointestinal effects of ashwagandha. Ashwagandha preparations are not currently regulated under the Therapeutic Goods Poisons Standard. Ashwagandha is not recognized as a food in Australia under the Food Standards Australia New Zealand.

The authors found that ashwagandha is used in many types of products distributed worldwide; however, dietary supplements are most common. Its use is subject to a wide range of requirements enforced at local and national levels covering manufacturing, formulation, labeling, marketing, and safety. The authors recommend a concerted effort to address safety concerns related to the human reproductive, immune, and central systems, thyroid hormones, and purported hepatotoxicity. Additionally, the authors state that manufacturers should conduct and publish product-specific toxicological investigations, disclose ingredient specifications, and non-proprietary assay methods to determine safe dosing and duration.

The authors declare no conflicts of interest.

—*Samaara Robbins*

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