



Ashwagandha: Navigating European regulations

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TAPPING EUROPEAN OPPORTUNITIES

The European market for supplements and herbal medicinal products continues to grow, offering suppliers and manufacturers new business and product development opportunities. Ashwagandha - a herbal extract in use for over 3,000 years - is attracting growing interest because of its clinically-backed benefits in addressing modern ailments. Successfully tapping this market, however, requires a full understanding of the European regulatory framework: the legislation that must be taken into account; the potential pitfalls; and the differences that still exist between Member States.

GROWING INTEREST AND MARKET POTENTIAL

Ashwagandha (*Withania somnifera* Dunal) is a small, woody shrub that belongs to the nightshade (Solanaceae) family. Taking about seven months to reach full harvest potential, it grows well in the dry arid drought-tolerant soil found in its native India. It can also be found in some parts of Asia, Africa and the Mediterranean.

The plant first appeared in the traditional Indian medical practice of Ayurveda and was used to enhance the movement of mind and body, an Ayurvedic principle known as vata. The root has historically been used to treat a range of internal conditions, from constipation and insomnia to nervous breakdown. This would have been crushed into a paste and mixed with water and consumed in beverage format. This tonic would also have been considered a diuretic, aphrodisiac and stimulant capable of raising metabolism. The bitter leaves were traditionally used topically, with a focus on fever and painful swellings.¹



Most current research has focused on the therapeutic effects of the root extract, and the plant has been recognised as having a range of potential applications. These now include cutting cortisol levels and stress and building muscle. Such broad applicability has made ashwagandha a focal point of industry interest.

EUROPE'S LEGISLATIVE CONTEXT

From an EU law perspective, ashwagandha is classified as an herbal ingredient used as a food supplement. Food supplements refer to foodstuffs that supplement the normal diet, and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect. In practice, this means that EU rules concerning the marketing of food supplements - and more specifically the use of herbal extracts as food supplements – apply.

There are certain key legislative provisions at the EU level that all suppliers and manufacturers keen to bring ashwagandha products onto the European market should be aware of. These include:

- **Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements²**

This Directive applies to all food supplements regardless of their composition. Only the rules applicable to the use of vitamins and minerals in the manufacture of food supplements are laid down in this Directive however; national rules concerning nutrients or other substances with nutritional or physiological effects used as ingredients of food supplements may be applicable.

The use of substances other than vitamins or minerals in the manufacture of food supplements – like ashwagandha for instance - therefore continues to be subject to national rules. Implementing measures are adopted by Member States to establish the specific values for maximum and minimum levels for vitamins and minerals present in food supplements.

Since EU law does not include specific provisions on the use of substances other than vitamins or minerals in food supplements, suppliers and manufacturers should be aware that the free movement of such products is governed by Articles 28 – 30 of the Treaty of the Functioning of the European Union³.

- **Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods⁴**

Article 8 of this Regulation establishes the procedure to be followed when a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods "... under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers".

This empowers the Commission to take preventive measures when a substance (other than vitamins or minerals) could harm human health.

- **Regulation (EC) No 178/2002 on the general legal framework and requirements of food law and the procedures applicable in the area of food safety⁵**

This Regulation is the key European act covering food safety legislation and applies to food supplements because they are considered foodstuffs. Relevant provisions for ashwagandha include Article 14 on the ban on the placing on the market of products which can damage the human health or are unfit for human consumption; Article 17 on primary responsibility to ensure that products comply with food law belongs to food business operations; and Article 18 on the obligation of food business operators to put in place a product traceability system. The Regulation also states that “where there are no specific EU provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed”.

- **Regulation (EC) 2015/2283 on Novel Foods⁶**

In the European Union (EU), ashwagandha is not subject to the Novel Food Regulation because it was on the market as a food or food ingredient before May 1997. Nonetheless, suppliers and manufacturers should be aware of this important piece of European legislation.^{2,4}

Dimitrios Apostolou, EU policy analyst / expert at Brussels-based regulatory affairs firm Shungham says that:

“The advantage of not being classified as a novel food is that your product is not subject to the Novel Foods legislation and various restrictions set by it.”

“There’s a very strict authorisation process in place. On the other hand, being covered by EU novel foods law would mean being obliged to comply with one simplified authorisation process as different national rules are not applicable.”

- **Regulation (EC) No 1924/2006 on nutrition and health claims⁷**

This Regulation lays down the conditions for the use of nutrition and health claims on food packaging. The decisive criterion for use of a health claim is that the health effect claimed in relation to a nutrient or substance must absolutely be based on scientific evidence. The clinical evidence supporting the properties of ashwagandha gives suppliers and manufacturers a key advantage here.



- **Directive 2001/83/EC on medicinal products⁹**

Suppliers and manufacturers of ashwagandha should be aware of this Directive. According to EU legislation, if the ingredient can be defined as a medicinal product, then the supplier will need to respect the provisions of this Directive. Herbal extracts can often be used as both food supplements and medicinal products. There are cases where the same product is authorised as a food in some Member States and as a medicinal product in others. Some herbal products like echinacea and ginkgo are indeed registered as medicinal products in certain Member States.

According to Dimitrios Apostolou (Shungham):

"The overall picture at EU level is that there is at present no EU regulation that defines the process for submitting authorisation on ashwagandha, when the latter is used as a food supplement. It depends on the Member State, but some EU Food Safety laws of general application still have to be complied with."

KEEPING TRACK OF NATIONAL DEVELOPMENTS

In addition to taking into account legislation at the EU level, suppliers and manufacturers must also keep track of developments at the Member State level. Because there are no harmonised EU rules on herbal extracts as food supplements (unlike for vitamins and minerals), it is up to national authorities to decide whether a product is safe, and which category it falls under (is the ingredient a food supplement or medicinal product?).

Many European countries are open to using ashwagandha in food supplements. Ashwagandha has been on some markets, such as Belgium and Hungary, for years. National rules can include so-called negative lists (prohibited botanicals), positive lists (permitted botanicals), and specific restrictions or modalities for use, including for example plant parts, maximum levels, labelling requirements in the form of warning statements. Some Member States have a more case-by-case approach, evaluating the final products at the time of food supplement notification or during market control.

The principle of Mutual Recognition applies to the use of ingredients (including botanicals) in food supplements not subject to harmonised EU legislation. Member States can only refuse the marketing of a product in its current form only where it can show that this is strictly necessary for the protection of, for example, health and life of humans.⁹ And because authorised botanicals are regulated at national level, this makes the proper functioning of the Mutual Recognition principle even more paramount, notes Claudia Mucciardi, Senior Regulatory Affairs Manager at Glanbia Performance Nutrition and an ESSNA (European Specialist Sports Nutrition Alliance) Vice-Chair. If one or more EU countries authorise the use of ashwagandha, then other EU markets should be able to benefit and accept the ingredient as well.

According to Claudia Mucciardi (ESSNA):

"It can be somewhat of a challenge when assessing compliance of botanicals, as they are not covered by harmonised EU legislation."

"Unfortunately, up until now businesses have not had confidence in the Mutual Recognition principle and have avoided using it. However, the EU Commission has plans to improve this principle and ensure that the principle functions properly without unsubstantiated refusals from member states. This should help support further innovation in the sector."

Belgium – a case study

In Belgium, ashwagandha is included in a positive list regarding the marketing and production of foods. The use of ashwagandha as a food supplement therefore will likely be permitted, provided that its safety is demonstrated. The procedure is based on the BELFRIT list¹⁰, a project of the Belgian, French and Italian authorities, which is designed to make life easier for business operators and is a step in the direction towards harmonisation. Basically, if you are selling supplements that include plant-based ingredients in the BELFRIT countries, you now have an official list to work with.

Germany – a case study

Germany is a key market for botanical ingredients, and while ashwagandha is approved for use, suppliers and manufacturers need to be aware that food supplements containing botanicals are evaluated on a case-by-case basis. This is to see whether they comply with the general legal provisions for food. Ashwagandha can be found on the German List of Herbal Substances as a substance used in both foods and medicines, though it advises that the ingredient should be on the list of substances for which restricted use in foods is recommended due to the presence of steroidal lactones (withanolides) and alkaloids.



FUTURE DEVELOPMENTS

The lack of harmonisation at the EU level means that suppliers and manufacturers must comply with individual national laws to penetrate domestic markets. Dimitrios Apostolou (Shungham) notes that the European Commission tends to harmonise areas of law falling within its shared competences and potentially affecting the effective functioning of the EU internal market, if national legislation has been proved inefficient to achieve the general objectives set by the EU:

“There are around 400 registered herbal ingredients on the European market at present, which suggests that this is the case.”

“It seems that the substance is commercially important when used as a food supplement and may accelerate the need for the EU harmonisation of its approval rules as a food supplement. This is perhaps an indication that harmonisation of herbal ingredients may be something for the future.”

WHY KSM-66?

KSM-66 Ashwagandha extract enables suppliers and manufacturers to deliver effective products that meet consumer demand while avoiding getting tangled up in regulatory red tape. The ingredient is recognised in most European Member States as a herbal ingredient safe for human consumption. On top of this, the targeted clinical studies that have been published in peer-reviewed journals give weight behind health claims. Some 15 pending health claims have been filed with EFSA, giving ashwagandha an advantage over other functional ingredients that are yet to start the health claims process. Under Regulation (EC) No 1924/2006 on nutrition and health claims¹¹, the decisive criterion for use of a health claim is that the health effect claimed in relation to a nutrient or substance must absolutely be based on scientific evidence. The clinical evidence supporting the properties of ashwagandha gives suppliers and manufacturers a key advantage here.

These studies show for example that KSM Ashwagandha root extract can be used for body weight management in adults under chronic stress¹²; for strengthening physical performance¹³; and increasing muscle mass and strength. This latter study confirmed that supplementation

could be useful in conjunction with a resistance training programme.¹⁴

Other trials have focused on cognitive function. A pilot study¹⁵ recently evaluated the efficacy and safety of KSM Ashwagandha in improving memory and cognitive functioning in adults with mild cognitive impairment.



Another clinical study¹⁶ examined whether high-concentration ashwagandha root extract could reduce female sexual dysfunction (FSD), which can result in reduced libido and pain during intercourse. Results suggested that “ashwagandha root extract could be useful for the treatment of FSD ... the lack of adverse effects suggests that the extract is safe to consume”.

CASE STUDIES



Dimitrios Apostolou,
Shungham

CASE STUDY 1. FINDING YOUR WAY THROUGH EUROPE'S REGULATORY MAZE

Dimitrios Apostolou, EU Policy analyst / expert in the field of food safety at Brussels-based regulatory affairs firm Shungham, provides a detailed guide around the potential pitfalls and current complexities surrounding food supplement legislation across Europe.

EU legislation provides a framework within which the food supplements and ingredients sector operates, but there is still room for controversy and confusion. Suppliers and manufacturers need to understand not only the key elements of this legislation but appreciate that regulatory differences at the national level exist.

Differences in classification

According to Dimitrios Apostolou (Shungham):

“The fact that a product is classified as a foodstuff in one Member State does not prevent it from being classified as a medicinal product in another if it displays the characteristics of such a product.”

“If the product is classified as a medicinal product, then it will then be subject to the corresponding rules of Directive 2001/83/EC even if it comes within the scope of other less stringent EU rules.”

This means that the provisions of the legislation applicable to medicinal products can apply to a product which also fulfils the definition of food supplement. Apostolou also notes that in order to market organic ashwagandha, suppliers and manufacturers must demonstrate that their product complies with EU requirements on the production and labelling of organic products of agricultural origin.

Another important issue is ensuring that substances other than vitamins or minerals used in the manufacture of food supplements comply with the national food safety legislation. Apostolou advises companies to check the positive lists of countries they wish to enter, to determine whether their supplement is already allowed on the domestic market.

Individual approaches

This reflects an overarching key issue: the extent to which individual European countries have their own approaches to approving ingredients. While Directive 2002/46/EC covers all food supplements with certain requirements and applies to all food supplements regardless of their composition, only rules applicable to the use of vitamins and minerals in the manufacture of food supplements have been laid down.

According to Dimitrios Apostolou (Shungham):

“Specific rules concerning nutrients other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements like plants and herbal extracts, could be laid down at a later stage.”

“But this depends on adequate and appropriate scientific data becoming available. Until such specific EU rules are adopted, national rules concerning nutrients or other substances with nutritional or physiological effects are applicable.”

Nonetheless, for ingredients other than vitamins and minerals, the European Commission has established harmonised rules to protect consumers against potential health risks. It maintains a list of substances that are known or suspected to have adverse effects on health; the use of these is therefore controlled.

“National control authorities are competent to decide, on a case-by-case basis, whether a given product falls within the definition of food (and not e.g. medicinal products), and if so, to which specific category of food it belongs,” adds Apostolou.



Tom Johnsson
Medicine Garden

CASE STUDY 2: USING EUROPEAN REGULATIONS TO YOUR ADVANTAGE

Europe’s complex regulatory framework presents a potential competitive advantage for suppliers and manufacturers of Ashwagandha KSM-66, according to Tom Johnsson, founder of Swedish supplements distributor Medicine Garden.

No one would argue that the European regulatory environment is straightforward. But having a natural ingredient with pending health claims that are backed by clinical studies can make life significantly easier for suppliers and manufacturers.

According to Tom Johnsson (Medicine Garden):

"The health claims that were filed with EFSA (European Food Safety Authority) back in 2004 cover everything from stress to sexual health."

"These are non-product specific, so any ashwagandha product can potentially use them. What makes KSM-66 unique, however, is that these claims are supported with targeted clinical studies; this is the secret behind the ingredient's success."

The complex regulatory framework gives KSM-66 users a competitive advantage, because including the ingredient in products poses fewer regulatory issues than with some other ingredients. While other ingredients continue to struggle to navigate the complexities of EU food law, a great deal of the hard work in making ashwagandha marketable has been accomplished. Some 15 health claims have been filed in total, and all have clinical support.

Tom Johnsson adds:

"If you take KSM-66 to the market you can compete with other adaptogens because you have claims that are supported with clinical studies."

Making claims your own

In order to stand out on the European market, suppliers and manufacturers need to ensure that their product is associated in the consumer's mind with specific health benefits. This has been key to the success of KSM-66. Significant investment has gone into clinical studies that provide targeted and specific scientific support.

Tom Johnsson (Medicine Garden) concludes:

"Very few ashwagandha suppliers have pushed the brand in this way."

"Investing heavily in clinical trials is a risk. But we knew that if we could achieve the number one position in the Swedish market, then we would be very hard to topple. This is what we have achieved. If you are number one you will always win – so long as you keep working hard."



LESSONS AND BEST PRACTICES

- There are at present no harmonised EU rules on the manufacturing and use of herbal extracts as food supplements
- While there are no EU-wide rules on submitting authorisations – this depends on the Member States – there are some general EU laws that demand compliance. Suppliers and manufacturers must be aware of legislation at both the EU and national level
- Ashwagandha can be classified as a food supplement in one Member State and a medicinal product in the other. This means that medicinal products legislation must be taken into account
- The use of nutrition and health claims on food packaging must be based on scientific evidence – there have been many published clinical trials supporting the efficacy of KSM-66 Ashwagandha
- Some Member States publish positive lists of ingredients that can be used in supplements, which will need to be checked
- The EU has left the door open for possible future harmonisation on herbal ingredients, as has been done with minerals and vitamins

The information provided here was compiled with due care and up to date to the best of our knowledge on publication.

You can find more information about KSM-66 Ashwagandha and the European market in the following white papers:

- Why Ashwagandha means business in Europe
- Ashwagandha: The right ingredients for success in Europe



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