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To: Ministerie van Volksgezondheid, Welzijn en Sport

Ahrensburg, 21.03.2025

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Amendment of the Commodities Act regulations in connection with the designation of harmful substances in food supplements and herbal preparations
Consultation procedure for the inclusion of *withania somnifera* in Annex I to the food supplement regulation

Ladies and gentlemen,

As part of a consultation process, there is currently a discussion whether *withania somnifera* should be included in Annex I of the food supplements regulation. Inclusion in Annex I of the regulation would lead to a ban on *withania somnifera* as an ingredient in food supplements in the Netherlands. We, the LEFO-Institute GmbH, would like to comment on this.

The LEFO-Institute GmbH is an independent commercial laboratory based in Ahrensburg, north of Hamburg, and has over 40 years of expertise in the field of food law consulting, particularly in the area of food supplements.

Over the past four years, *withania somnifera* as ingredient in food supplements has been the subject of discussions on the EU level and public interest in this ingredient has increased significantly. Therefore, it is important to evaluate this herbal raw material and its safety.

Roots of *withania somnifera* are traditionally used in ayurvedic nutrition and have been permitted ingredients in food supplements for many years. Based on the Food Safety and Standards regulation (2022) of the Indian government, daily doses of 3-6 g of root powder or 0.5-1 g of extract are considered safe in ayurvedic nutrition. In the European lists of substances (BelFrIt 2014, Belgium 2021, France 2019, Italy 2022, Poland 2022) the use of the entire plant, as well as flowers, green aerial part and roots, are permitted ingredients in food supplements.
In Germany the root is according to the list of substances of the Competent Federal Government and Federal State Authorities (BVL list 2020) classified as a food with a maximum limit. This list is not legally binding, but reflects the national view of Germany, Austria and Switzerland.
In the current Novel Food catalogue of the European Commission, all parts of the plant are classified as not novel in food supplements. The non-concentrated aqueous infusion from the roots is classified as not novel in food. This shows that the roots have a long history of use as safe food ingredient or food supplement ingredient. The entries in the catalogue, which was compiled by a working group of the European Community as a guideline with regard to regulation (EC) No. 258/97, incorporate the findings of the European Commission and the authorities responsible for novel foods in the member states. Therefore, *withania somnifera* has been safely used as a component of the usual diet in the European Union for at least 25 years.

Since the root is also used as a pharmaceutical drug according to the BVL list of substances, a maximum limit for the root in food is recommended. According to the regulation (EC) 178/2002 and the Directive 2002/46/EC, food/food supplements must be clearly distinguished from pharmaceutical

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drugs. The BVL list of substances specifies a therapeutically effective dosage of 3-6 g of root powder per day based on the WHO monograph (2004).

In Germany, we are not aware of any medicines containing *withania somnifera* or withanolides as an active ingredient. As such, a therapeutically effective dosage for the plant or the specific components cannot be derived at this time. An analysis of the withanolides and alkaloids is recommended as part of the quality assurance of the raw material.

Poland is so far the first European member state, who limits the content of withanolides in food supplements. The Polish list of substances (2022) states that the content of 10 mg of withanolides must not be exceeded with the recommended daily intake in the product.

In the "WHO monographs on selected medicinal plants" (Volume 4, 2009), the WHO stated that the use of *withania somnifera* during pregnancy and breastfeeding is not recommended due to a lack of data. However, more recent studies indicate that the use of the root during pregnancy and breastfeeding is safe. In addition, the Australian Complementary Medicine Organization (CMA) stated in 2019 that such a warning contradicts traditional use, as *withania somnifera* roots are considered safe in a normal dosage.

The Danish Veterinary and Food Authority (Fødevarestyrelse) regularly compiles a list of plants and other substances in food supplements that are assessed in advance via a risk assessment with regard to their food safety. The current risk assessment (2020) on *withania somnifera* states that the root, root extracts and extracts from other parts of the plant could have an effect on the thyroid, sex hormones, central nervous system and liver. However, the results of the animal and human studies presented are not consistent, so the safety of *withania somnifera* and its preparations cannot be proven. The Danish Veterinary and Food Authority has banned the sale of food supplements containing *withania somnifera* since 2023.
In their risk assessment five reported cases of liver damage in Iceland and the USA are listed. However, no precise information was provided regarding products containing *withania somnifera*, like composition of the consumed products, the amount consumed or the composition of the extracts. Without further information on the products, a clear connection between liver damage and the consumption of *withania somnifera* cannot be established.

According to the Polish list of substances (2022), food supplements containing less than 3 g of *withania somnifera* root powder per day or less than 10 mg of withanolides must contain a consumer notice. Consumer groups such as children, pregnant and breastfeeding women, as well as people taking medicines such as hypnotics or antiepileptics should not consume such a product.

The competent authority in France for food safety, environmental protection and occupational health and safety (ANSES) has re-evaluated current studies in its opinion (April 2024) and concluded that the safety of *withania somnifera* still cannot be proven due to the lack of data. The ANSES does not recommend the use of food supplements containing *withania somnifera* for the following consumer groups: people under 18 years of age, pregnant and breastfeeding women, people with endocrine disorders, people with liver and heart problems, and people receiving treatment with a depressant effect on the central nervous system.

The German Federal Institute for Risk Assessment (BfR) responded to the current data on *withania somnifera* in the EU in September 2024. The consumption of *withania somnifera* preparations is not recommended for children, pregnant and breastfeeding women and for people with existing or previous liver disease.

Based on the current notifications in the various European member states, a warning for products containing *withania somnifera* for children, pregnant women and breastfeeding women is understandable. Since the studies regarding the negative influence on the thyroid, immune system, central

nervous system and liver are not clear, in our opinion an explicit warning for these consumer groups cannot be required.

To date, the use of *withania somnifera* as an ingredient in food supplements is prohibited in only one member state and is subject to clear conditions of use in one member state. In the other Euopean Union member states, *withania somnifera* is a permitted ingredient in food supplements.
In our opinion, a planned inclusion of withania somnifera in Annex I of the regulation and thus a ban on this ingredient in the Netherlands should not take place without prior review by the European Food Safety Authority (EFSA). In this respect, an orderly procedure pursuant to Article 8 of the regulation (EC) No. 1925/2006 is appropriate. The Food Supplements Working Group, which consists of heads of Food Safety Agencies of the 27 European countries, stated in its report (2024) that, among other things, *withania somnifera* should be evaluated by the EFSA. The EFSA's review should clarify whether the European Commission should restrict or prohibit the use of *withania somnifera* by including it in Annex III to regulation (EC) No. 1925/2006.

Summary:

The root of *withania somnifera* is known and marketable in Germany and the EU as a food ingredient with a recommended maximum limit. In our opinion, a general ban on *withania somnifera* as an ingredient in food supplements is therefore not understandable. Based on the information provided by the WHO and the European substance lists, it is obvious that conditions of use for *withania somnifera* should be defined and *withania somnifera* should be included in Annex II or Annex III of the food supplements regulation. Therefore a special note should be made for the consumer group “children, pregnant women and breastfeeding women” based on the current data. Since the study situation regarding the negative influence on the thyroid, immune system, central nervous system and liver is not clear, we believe that an explicit warning for these consumer groups cannot be required.

It is our opinion, that regarding the goals of a harmonized EU market for foodstuffs, isolated national bans of food should stay strictly minimized, to maintain consumers and producers confidence in legislation and authorities of the European Union.

With kind regards,

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authorised expert in analysation and evaluation of foodstuffs (ö.b.u.v.)

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