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COMMENTS ON THE PROPOSED AMENDMENT OF THE COMMODITIES ACT REGULATIONS

This letter constitutes the response of the Alliance for Natural Health Europe to the proposed Amendment of the Commodities Act Regulations in connection with the designation of harmful substances in food supplements and herbal preparations.

The Alliance for Natural Health (ANH) is a non-profit organisation, founded in 2002, representing around one million consumers, practitioners and companies around the world with a mission to protect and promote natural health, using the tools of good science and good law. We have three offices: in Amsterdam (ANH Europe; anheurope.org), the UK (ANH International; anhinternational.org) and the USA (ANH USA; anh-usa.org).

We are deeply concerned about the draft legislation that proposes adding ashwagandha (*Withania somnifera* (L.) Dunal) to the list of prohibited plants and fungi in the Netherlands. If the draft legislation were to pass into law and the prohibition on any use of ashwagandha were to be upheld, a very troubling precedent would be set. This would not only increase legal uncertainty over the use of many other botanicals that have long histories of safe use as food supplements both within the Netherlands and beyond, it would also likely increase public exposure to inferior quality or adulterated products on grey or black markets that could pose a very real and significant health risks to the ever growing number of Dutch citizens who are choosing to use adaptogenic herbs to help combat the persistent levels of chronic stress that are associated with our modern lives. Apart from ashwagandha, other adaptogenic herbs that are widely used include Rhodiola (*Rhodiola rosea*), Siberian ginseng (*Eleutherococcus senticosus*), Schisandra (*Schisandra chinensis*), and Asian ginseng (*Panax ginseng*).

We have laid out each of our principle concerns in the 4 points below:

1. **Risk assessment.** As RIVM has recognised, there have been limited numbers of recent case reports concerning liver toxicity[1] associated with use of ashwagandha, adding to the extensive evidence of the herb's effects, typically beneficial ones, on the endocrine, nervous and immune systems.[2] Monographs

[1] Lubarska M, Hałasiński P, Hryhorowicz S, Mahadea DS, Łykowska-Szuber L, Eder P, Dobrowolska A, Krela-Kaźmierczak I. Liver Dangers of Herbal Products: A Case Report of Ashwagandha-Induced Liver Injury. *Int J Environ Res Public Health*. 2023 Feb 22;20(5):3921.
[2] Wiciński M, Fajkiel-Madajczyk A, Kurant Z, Kurant D, Gryczka K, Falkowski M, Wiśniewska M, Słupski M, Ohla J, Zabrzyński J. Can Ashwagandha Benefit the Endocrine System?-A Review. *Int J Mol Sci*. 2023 Nov

on ashwagandha[3,4,5,6,7] refer to the general safety of ashwagandha preparations when used at dosages up to 6.5g dry weight of root (or equivalent) per day. Ashwagandha, like many botanicals exhibits a bi-phasic, or hormetic, dose-response, so the effects at lower doses are quite different from those at higher doses. Given the presence of steroidal lactones, it is unsurprising that adverse effects relating to hormonal imbalances may be able to be induced at very high levels of exposure, as has been demonstrated in a number of animal studies (see below). While it is clear that ashwagandha-associated liver injury has been reported in the literature, RIVM has not attempted to establish causality, which would require use of the Council for International Organizations of Medical Sciences Scale (CIOMS), also known as RUCAM (Roussel Uclaf Causality Assessment Method) for assessing herbal-induced liver injury. It is essential that any risk assessment that is used as a basis for outright prohibition establishes that normal, recommended use patterns of the botanical in question induce significant risk. As noted above, there is no evidence that any significant risk to human health is posed to adults at exposures up to 6.5g dry weight of root (or equivalent) per day. Misinterpretation of safety concerns over the use of ashwagandha by the Danish government was addressed by McGill University in Canada,[8] and these same misinterpretations appear to have been made by the RIVM, which, unlike Germany, appears to have not recognised the previous misinterpretation of hepatotoxicity data relating to kava kava (*Piper methysticum*)[9], that caused the government of Germany to reverse its ban on the herb in 2014 following legal action.[10]

20;24(22):16513.

[3] American Herbal Pharmacopoeia: https://herbal-ahp.org/online-ordering-ashwagandha-root/?utm_source=chatgpt.com.

[4] Health Canada: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/dblmages/mono_ashwagandha_english.pdf.

[5] Egyptian Herbal Monograph: https://www.edaegypt.gov.eg/media/5fndqisx/withania-somnifera-l-dunal.pdf.

[6] Alternative Medicine Review: https://chiro.org/Graphics_Box_NUTRITION/Withania_somnifera_Ashwagandha_Monograph.pdf

[7] Pakistan Journal of Nutrition: https://www.researchgate.net/publication/350895960_Monograph_of_Withania_somnifera_L_Dunal.

[8] McGill University, "Why Did Denmark Ban Ashwagandha?", 2 June 2023: https://www.mcgill.ca/oss/article/critical-thinking-health-and-nutrition/why-did-denmark-ban-ashwagandha.

[9] Teschke R, Fuchs J, Bahre R, Genthner A, WolW A. Kava hepatotoxicity: comparative study of two structured quantitative methods for causality assessment. *J Clin Pharm Ther* 2010; 35: 545-63.

[10] Kuchta K, Schmidt M, Nahrstedt A. German Kava Ban Lifted by Court: The Alleged Hepatotoxicity of Kava (Piper methysticum) as a Case of Ill-Defined Herbal Drug Identity, Lacking Quality Control, and Misguided Regulatory Politics. *Planta Med.* 2015 Dec;81(18):1647-53.

2. **Traditional use patterns**: The WHO Monograph on ashwagandha indicates the following:

> ***Uses described in pharmacopoeias and well established documents***
> As a general tonic to increase energy, improve overall health and prevent disease in athletes and the elderly.

This statement is linked to two references:

- The Ayurvedic Pharmacopoeia of India Part I, Vol. I, 1st ed. New Delhi, Government of India Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, 1990 (reprinted 2001).
- Mishra LC, Singh BB, Dagenais S. Scientific basis for the therapeutic use of Withania somnifera (Ashwagandha): A review. *Alternative Medicine Review*, 2000, 5:334–346.

A broader perspective on traditional usage of ashwagandha in Ayurveda can be derived from Pharmacopoeia monographs[3-7] and includes its use as an adaptogen and rejuvenator where it enhances stamina, vitality, and resilience to physical and mental stress; for general debility, weakness, and fatigue; as a nervine tonic and sedative, to calm the nervous system, reduce anxiety, and promote restful sleep, to help address insomnia and nervous exhaustion; as an anti-inflammatory and analgesic to help support conditions like arthritis, joint inflammation, and chronic pain, and; as an immunomodulator and aphrodisiac: where it is to believed to boost immunity and increase fertility, including sperm quality.

While all parts of the plant have been used in traditional Indian (as well as Chinese) medicine, it is the roots that are most commonly used for internal purposes. Preparations are normally delivered as a powder, decoction, or infused in oil or ghee.

There is no evidence of recent use of ashwagandha as an abortifacient (a substance that induces miscarriage) or as an emmenagogue (a substance the induces menstrual flow). Such references to these uses are limited to ancient texts, that include mention of the plant's "garbhapatana" (abortifacient) and "garbhasraava" (emmenagogue) properties at very high dosages. These properties and uses are mentioned in the three following ancient Ayurvedic texts: *Charaka Samhita*, which mentions the use of ashwagandha in formulations promoting menstrual flow and expelling retained products of conception, in the *Sushruta Samhita,* refers to ashwagandha in combination with other herbs as a uterine stimulant for incomplete abortions, and the *Bhava Prakash Nighantu*, which lists *Withania somnifera* as a "garbhapatana dravya" (abortifacient herb) and provides dosage recommendations in traditional preparations. Typically

dosages used are in the 10-15g dry root per day, often in divided doses, along with her abortifacient herbs.[11] There are limited rodent studies[12,13,14] that point to the herb's potential properties as an abortifacient, but the doses used relative to animal body weight are extremely high.

Responding to the Danish government's concerns over ashwagandha's purported abortifacient properties, Dr Roy Upton, President of the American Herbal Pharmacopoeia, stated in a press release on the subject in June 2024[15]: "…In addition, subsequent to safety concerns raised in the European Union, the Ministry of AYUSH (Government of India) released a Safety Dossier (2.0; 2024) noting the lack of abortifacient activity of ashwagandha root and citing all clinical and pre-clinical data that have investigated the use of ashwagandha and its preparations in pregnancy. One toxicity investigation in rats demonstrated a No Observed Adverse Effect Level of ashwagandha root extract of 2,000 mg/kg. The available human trials reported no maternal or fetal toxicity in pregnant women using ashwagandha preparations. No other clinical or pre-clinical investigations revealed an abortifacient activity."

This report[16] was authored by an expert committee convened by the Ministry of Ayush to investigate, and subsequently attempt to dispel, the Danish government's concerns.

3. **Emerging use patterns in Europe and the USA.** The National Institutes for Health (USA) LiverTox database,[17] updated in September 2024, states as follows: "Ashwagandha is a popular Ayurvedic herb used as a general tonic, to improve health, increase energy and reduce stress and anxiety. Ashwagandha has not been implicated in causing serum enzyme elevations during therapy but recently has been implicated in cases of clinically apparent liver injury." It appears highly likely that such cases are the result of changes in non-traditional usage triggered by increased demand, the very situation that was seen when demand for kava in

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[11] Sadananda Sharma, *Rasatarangini*, Chapter 24 – Lists *Withania*'s properties and therapeutic uses.

[12] Bhadauria S, Nirala SK. Uterine stimulant effects of *Withania somnifera* in rats. *J Ethnopharmacol*. 2002;81(2):205-209.

[13] Anbazhagan S, Kataria JM, Varma MC, et al. Embryotoxic and fetotoxic potential of Withania somnifera in rats. *Toxicol Appl Pharmacol*. 2003;190(3):222-228. doi:10.1016/S0041-008X(03)00182-2.

[14] Devi PU, Sharada AC, Solomon FE. Anti-implantation effect of *Withania somnifera* in Wistar rats. *Indian J Exp Biol*. 2006;44(9):750-754.

[15] American Herbal Pharmacopoeia press release, June 23, 2024: https://herbal-ahp.org/wp-content/uploads/2024/07/Press-Release-Ashwagandha-Abortifacient-Assessment_06-24-2024.pdf.

[16] Safety of Ashwagandha (*Withania somnifera*). Report of the Expert Committee constituted by the Ministry of Ayush, Govt. of India (2024): https://ayush.gov.in/images/domains/quality_standards/safetyReportAshwagandha.pdf.

[17] NIH LiverTox entry for ashwagandha: https://www.ncbi.nlm.nih.gov/books/NBK548536/.

Europe increased during the late 1990s. Increased demand could lead both to changes in the plant parts used, as well as in the processing methods. Accordingly, we propose that there are two main changes to traditional use that should be investigated prior to instigating any outright ban:
a) A potential shift to including non-root parts, in particular leaf, and;
b) Use of supercritical (carbon dioxide-based), or highly concentrated ethanolic or methanolic extracts that may either greatly increase the concentration of steroidal lactones and/or alter their profile, compared with those found in traditional preparations.

4. **Legal proportionality.** Any total prohibition of an herb, regardless of the botanical parts used, the method of processing or production, or its dosage (exposure), should be able to able to be justified unequivocally. This would require a high degree of scientific conclusivity in which it could be demonstrated that *any* amount of the botanical substance poses a significant risk to health. This is simply not possible in light of the totality of available evidence, including adverse reports, on the use of ashwagandha in its traditional forms, or in contemporary forms that do not change significantly the exposure to bioactive compounds that are known to be able to induce harmful effects at high exposures. It follows that there is no legal rationale for an outright ban, and a proportionate risk management approach that would still err on the side of caution, would involve: 1) limiting the total daily of dosage of dried root (or equivalent) to 6.5g; 2) regarding use of any botanical part other than the root as an adulterated and therefore illegal food supplement, and; 3) requiring warning statements on labels, advising against the use of ashwagandha during pregnancy, unless directed otherwise by a health professional. Any risk management approach that is more restrictive than this could be deemed legally disproportionate and may need to be tested in the courts.

Conclusion

On the basis of the concerns detailed here, in addition to the concerns expressed in over 500 other consultation responses, we are hopeful that the government of the Netherlands will reconsider its proposed outright ban on ashwagandha. Such a ban seriously impedes consumer choice and will likely increase the risk of imports of sub-standard quality products that may actually increase public health risk.

We urge the Netherlands government to proceed by using a rational risk assessment approach that allows both consumer choice and prevents potentially harmful herbal products from entering the market.

Such a proportionate risk assessment approach could easily be achieved by:
1) limiting use of ashwagandha to a daily dose of 6.5g dry weight (or equivalent), 2) by excluding all botanical parts except root, and 3) including a mandatory warning that advises consumers to avoid use during pregnancy.

Should you have any queries that emerge from consideration of our consultation response, please do not hesitate to contact us.

Faithfully,

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Scientific Director
ANH Europe