Ashwagandha

Status: Closed
Date launched: 8 July 2024
Closing date: 2 September 2024

Summary of responses

Summary of responses to call for evidence on Ashwagandha

This call for data will be of most interest to?

We welcome data from food business operators (FBOs), experts in the field, trade organisations, international organisations, local authorities, consumers and those undertaking research in a topic related to this call for evidence.?

FBOs who manufacture, process, distribute, use, sell or import food supplements containing ashwagandha are encouraged to participate.

Purpose of the call for evidence

The purpose of this call for evidence is to gather information on ashwagandha food supplements in order to build an evidence package which will be assessed through the FSA's risk analysis process. Outputs will include a risk assessment and evidence base which will inform any future risk management advice including possible risk management options to be presented to Ministers.

How to respond

Responses to this call for evidence should be sent to ashwagandha-callforevidence@food.gov.uk

Details of call for evidence

Ashwagandha (also known as Withania somnifera) is a herb which is used to make various traditional remedies. The popularity of ashwagandha in food supplements has increased over recent years, including media exposure which associates ashwagandha with relieving stress and anxiety, promoting sleep and boosting focus.

In the UK there are no safe levels established or set limits for its use in food supplements.

Risk assessments conducted through literature reviews have shown association with effects on thyroid hormone levels and reports of thyroid toxicity, hypoglycaemic effects, and potential liver toxicity.?

As we are aware there are potential risks to health from consuming ashwagandha in food supplements, the FSA is issuing this call for evidence to support our request for a risk assessment from the Committee on Toxicity for ashwagandha. The purpose of this work is to

determine whether a safe level of ashwagandha for use in food supplements can be established, whilst at the same time assessing the risks associated with consuming food supplements containing ashwagandha.

Novel Food Status???

Novel Foods are foods which have not been consumed to a significant degree within the UK or EU before 15 May 1997.?All novel foods are required to undergo a mandatory pre-market safety assessment and authorisation under Assimilated Novel Food Regulation 2015/2283? before they can be legally marketed in Great Britain. Further information is available via the Novel foods authorisation guidance.

Non-concentrated aqueous infusion from the roots

There is evidence that a significant history of consumption exists for the non-concentrated aqueous infusion from the roots of Ashwagandha as a food in the UK/EU prior to 15 May 1997 and therefore it does not fall within the scope of Assimilated Regulation 2015/2283, relating to novel foods.?However, like all foods sold in the UK, such products should comply with Assimilated Regulation (EC) 178/2002, relating to General Food Law. It should also be clearly labelled and inform consumers as to the exact nature of the food.??

All plants parts

All plant parts of Ashwagandha are not considered novel for use as food supplements but are considered unauthorised novel foods for all other food uses. Therefore, businesses who wish to use it in any foods (other than food supplements) would need to gain authorisation as a novel food for that use before introducing the product to the market in Great Britain.??

Evidence required

We are interested in receiving:

- any available information/data on the safety assessment of food supplements containing ashwagandha, including toxicological testing and relevant toxicological data (this can include any communication you have received by consumers reporting any potential adverse effects)
- any testing that has been carried out that informs the safety and stability ashwagandha in its proposed use
- any scientific evidence used to support claims being made
- any sourcing information and specifications of the plant part material used
- the final product’s full list of ingredients (including ratios/percentages) and specification. This also includes any available information on levels of contaminants (such as heavy metals) in the final product
- information on the types of products on the market and which are the most prevalent (for example food supplements containing dried root or food supplements containing ashwagandha extract)
- any information on the specialised formulation that is intended to modify the absorption or metabolism of the supplement, e.g. nanoformulation
- any relevant information regarding the manufacturing process, including control processes used, such as testing for pesticides, contaminants etc. In the cases of extracts information any information on the types of extraction and the chemicals used in extraction is also needed

- consumer information to better understand our audience. Please provide any market/sales data on ashwagandha food supplements, including any consumer demographics info such as age, sex and other relevant characteristics. Any information specifically related to consumption/sales to pregnant women or children is welcome
- any other pertinent information or issues concerning these products

All information received will be reviewed and form part of the Committee on Toxicity's wider consideration of food supplements containing ashwagandha. Information will be subject to the FSA's obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004 and to the extent such information contains personal data it will be processed in accordance with our Privacy notice for consultation.

Similarly, information will also be subject to?FSS's obligations under the Freedom of Information (Scotland) Act 2022 and The Environmental Information (Scotland) Regulations 2004. Commercially sensitive information and/or information confidential in nature should be specifically identified in your response. This will be considered in conjunction with the requirements outlined above.

Deadline for responses

Responses are required by **close of 2 September 2024**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Please send response to ashwagandha-callforevidence@food.gov.uk

Information handling

For more information on how the FSA handles your personal data, please refer to our Consultation privacy notice and the information handling section on our calls for data page.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

Thank you on behalf of the Food Standards Agency for helping to ensure that our policy development is supported by a robust evidence basis.

Standards Policy Team, FSA in Wales