

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
ROBUVIT® - DOSSIER 198**ISSUE**

1. The German Competent Authority (CA) has prepared an initial assessment report on an application for Robuvit® (dried aqueous extract from *Quercus robur* oak wood) under the Novel Foods Regulation (EC) No 258/97.
2. The Committee is asked whether it agrees with the initial opinion that further assessment of the application is required and whether it would like to make any further comments on this application to inform EFSA's assessment. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 6 June the European Commission forwarded the Federal office for Consumer Protection and Food Safety's initial opinion, which recommended a further evaluation by EFSA, on an application made by analyse & realize GmbH under Article 4 of the Regulation for Robuvit® (dried aqueous extract from *Quercus robur* oak wood)
4. The Commission has requested the views of Member States on the German CA's initial opinion. Member States have until 4 August to submit any comments and/or reasoned objections to the German assessment.
5. The application dossier is attached as **Annex A**, the German Initial Assessment Report is attached as **Annex B**. **Annex A** and **B** contain protected information.

This application

6. Robuvit® is a light to dark brown powder with a characteristic smell and woody taste (of humic substances, tannings and wood)
7. The applicant intends Robuvit® to be used in food supplements with a recommended intake of a maximum of 300mg per day. The applicant states that it has been marketed in the USA since 2014 as an ingredient in food supplements at a daily dose of 200mg. The applicant has not provided an explanation as to why the dose in Europe is higher than the dose used in the

USA. In the absence of human data the German CA therefore recommended that the intended maximum daily intake be lowered from 300 to 200mg.

8. The applicant states that oak wood (*Quercus robur*) is listed in the US EAFUS (Everything added to Food in the US). Oak white chips are on the list as a substance which is used in conjunction with flavours (white oak is usually American white oak (*Quercus Alba*)). Oak (English) Wood is listed as used in conjunction with flavours in alcoholic beverages only).
9. The German CA considered the genotoxicity study had a statistically significant increase in the number of binucleate cells with micronucleae which it considered needed further exploration. The applicant was asked to explain these results but did not present any relevant new information. The German CA considered the genotoxicity information of the product was not sufficient to demonstrate the safety of the novel ingredient and recommended that in accordance with Article 6(3) of Regulation 9EC) no 258/97 the application is further assessed by EFSA pursuant to Article 7 of the Regulation.
10. In the initial opinion no microbiological concerns were expressed. Following stability testing a shelf life of 24 months was proposed by the applicant when the product is stored in polystyrene bags in cardboard boxes at room temperature and relative air humidity of 60%.
11. The initial opinion suggests the German CA had no concerns on allergenicity. The opinion states that to date, oak bark has not been found to have allergenic properties. As the identity of the protein in the product was not known it was not possible to carry out bioinformatics comparative analysis.

COMMITTEE ACTION REQUIRED

- Members are asked whether they agree with the initial opinion from the German CA and whether they wish to make any comments on the application.
- The Committee's advice will form the basis for the UK's formal response to the opinion of the German CA.

**Secretariat
July 2017**

Annexes attached:

Annex A Application dossier for the approval of Robuvit®

Annex B Initial Opinion of the German Authorities