

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

COMMENTS FROM THE COMMITTEE ON THE ONE YEAR TOXICOLOGY STUDY ON TONGKAT ALI ROOT EXTRACT: RESPONSE FROM THE APPLICANT

Issue

At the September 2016 and subsequent meetings the Committee has reviewed the dossier submitted in support of the application for authorisation of Tongkat Ali Root Extract under the Novel Foods Regulation (EC) 258/97. The Committee had requested further information on a number of aspects of the dossier including the toxicology studies summarised in the dossier. The Committee were particularly interested in examining the original data from the one year toxicology study. This paper presents the Committee's comments and conclusions on this study and the applicant's response.

Background

1. At the early ACNFP meetings at which Tongkat Ali was discussed the Committee expressed concern regarding the way the conclusions of some of the toxicology studies were summarised in the dossier and the extent to which individual adverse results were dismissed as not biologically relevant. As a result the Committee asked to see the original data for the one-year toxicology study and carried out a detailed analysis of the data presented.
2. The Committee has also sought clarification on a number of other areas. These are not addressed in this response and the Secretariat has sought further information on these areas which will be addressed separately.

Analysis of the one year toxicology study

3. The results of this analysis by the ACNFP are presented in **Annex A** attached to this paper and consists of initial general comments on the study followed by more detailed observations including: possible immune system effects, renal effects and liver enlargement. The comments from the Committee were shared with the applicant and an opportunity given for them to respond.

Response from the applicant

4. The applicant's detailed response to the Committee's comments is attached as **Annex B**. Annex B contains sensitive information. In their response the applicant has again provided arguments to explain the different categories of adverse effects recorded in the study but has not addressed the need for a more holistic approach.
5. Nevertheless the applicant has accepted the Committee's advice on lowering the overall intake levels for Tongkat Ali and in order to achieve this has proposed limiting the number of products containing the NI to supplements and caffeine containing beverages.
6. They have also provided an updated intake assessment based on these criteria, which considerably lowers the overall population exposure levels

Committee action sought

7. The Committee is asked to consider the detailed response of the applicant regarding the one-year toxicity study and to decide whether:
 - It is content with the applicant's response in relation to the toxicological outcomes of the study
 - The intake and exposure data presented are adequate to determine whether the NI complies with the criteria for acceptance under the novel food regulation in relation to population exposure and intake levels.
8. If so, the Committee is asked whether it is content to recommend approval for the NI to be used in the proposed food products at the proposed levels.
9. If not, the Committee is invited to identify what further data or information should be provided.

**Secretariat
September 2017**

Annexes attached

Annex A: Tongkat Ali one year toxicity study: Views and comments from the ACNFP

Annex B: Biotropics Tongkat Ali response to comments from ACNFP