

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CLINOPTILOLITE

ISSUE

Members considered this application for the authorisation of clinoptilolite as a novel food ingredient, at their February 2004 meeting. As Members highlighted a number of concerns that have not been answered by the applicant, the Committee is asked to consider a draft opinion refusing the placing on the market of this novel food ingredient, due to a lack of adequate safety data .

BACKGROUND

1. An application was submitted by Euremica Environmental Ltd. for authorisation of clinoptilolite as a novel food ingredient in the EU. The UK Competent Authority accepted this application on 5th January 2004 and in accordance with Article 6(3) of the novel food regulation (EC) No 258/97, the UK had 3 months to prepare an initial assessment report.
2. The ACNFP considered the application at its meeting in February 2004 (ACNFP/64/3) and raised a number of concerns, which were forwarded to the applicant by the Secretariat on 23 February 2004. The applicant was advised that the 3 month period for initial assessment could be extended in order for him to respond to the concerns. A copy of the application dossier and the letter detailing Member's concerns are attached as Appendix 1 and 2 respectively.
3. The applicant has not supplied any additional information for members to consider and has indicated to the Secretariat that they do not intend to do so.
4. The Secretariat is therefore of the view that the evaluation should be concluded and, in view of the various unanswered concerns, a negative opinion for this novel food ingredient should be issued. Once the UK's initial assessment report on is finalised, the European Commission will circulate it to the other European Competent Authorities for comment.

Committee Action required

5. The Committee is invited to consider and comment on the draft initial opinion on Euremica Environment's application provided in Appendix 3 and to indicate whether it is an accurate reflection of their assessment of this NI.
6. In line with the Committee's standard practice, the draft initial opinion will be published via the website for a short period of public comment. Once the Committee has considered any comments that are received, the initial assessment will be forwarded to the Commission and will form the basis for the UK's formal assessment of this application.

**Secretariat
September 2005**

Appendices attached

Appendix 1: Application dossier

Appendix 2: Letter detailing the ACNFP comments

Appendix 3: Draft opinion (restricted)

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Application dossier.

This document has been published on the Food Standards Agency website at:

<http://www.food.gov.uk/science/ouradvisors/novelfood/assess/fullapplies/clinoptilolite/>

**Secretariat
September 2005**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter detailing the ACNFP comments.

**Secretariat
September 2005**

Mr Rob Sampson

By E-mail

23rd February 2004

Reference: NFU 471

Dear Rob,

As you are aware, the ACNFP recently considered your application for the approval of Clinoptilolite under the Novel Foods Regulation (EC) 258/97. The Committee raised a number of concerns over the product to which they requested responses before the assessment of the product can continue.

The Committee raised concerns over the identity of the protein present in the product and noted that treatment at 100°C was insufficient to ensure complete denaturation of protein. Members therefore requested a characterisation of this protein, in order to assess potential allergenicity. They also considered that the proposed heat treatment was insufficient to kill any spores that may be present in the product such as Clostridium spores and requested that analyses were carried out for spore-forming organisms.

Members observed that clinoptilolite has been demonstrated to interfere with the absorption or activity of medicines and nutrients such as beta-carotene and may also interfere with the activity of gut hormones. The Committee therefore recommended that further oral studies must be carried out to demonstrate the extent of this interference and therefore demonstrate the safety of this product.

The Committee considered that the toxicity studies provided were insufficient due to lack of study detail and the lack of chronic studies. The product is to be consumed on a chronic basis and the data provided did not give sufficient reassurance of safety.

Members would want to see more human oral studies carried out on the product as the information on human consumption does not offer reassurance of the safety of this product as a foodstuff at the anticipated levels of consumption. Laboratory animals receive a diet rich in trace elements whereas many humans do not. There were concerns that the product may remove essential trace elements from the gut and this effect would not be evident in laboratory animals.

The Committee voiced concerns over the possibility of crystalluria due to the high silicon content of the product, especially in people with existing kidney problems.

Members suggested that either a dose for children should be indicated on the container or the label should state that the product is not for consumption by children.

It may be useful for us to meet to discuss the options that are open to you following this meeting. If you would like to arrange a meeting, please contact us to arrange a suitable date.

Yours sincerely

Frances Cleaver

Novel Foods Division.