

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

BEE VENOM FOR ADDITION TO HONEY

Issue

This paper supplements ACNFP/94/1 by summarising Members' original written comments on this novel food application and reporting on comments submitted by members of the public. In addition, the applicant has provided additional information in response to these comments.

Background

1. Due to the cancellation of the July meeting, Members were invited to provide written comments on this application to the Secretariat.
2. A letter detailing the Members' comments on this application was sent to the applicant on 4 August (see **Annex 5**), covering the following areas:
 - i) concerns were expressed that consumption of bee venom has the potential to cause allergic reactions including anaphylaxis:
 - ii) concerns were expressed that wider use of bee venom (including use in the EU) may increase the potential for allergenic responses:
 - iii) members were interested in the cell culture study presented in the dossier concerning the induction of prostaglandin E2 production and asked whether any other prostaglandins are also affected:
 - iv) members noted that the addition of bee venom to honey may induce some consumers to consume more honey which in turn may result in an increased risk of dental caries; and
 - v) members questioned the efficacy of bee venom, based on analysis of the data presented in the human clinical trial in the dossier.
3. As reported in ACNFP/94/1, the dossier was placed on the ACNFP website for public comment. Eight comments were received which largely expressed concerns relating to potential allergenicity of this novel ingredient and concerns relating to the welfare of honey bees. These comments are summarised in **Annex 6**. Additionally, 115 comments were received from customers who regularly use honey products with bee venom. All but one of these commentators expressed

satisfaction that bee venom products helped to alleviate arthritic symptoms. The remaining comment was of a more neutral nature.

4. The applicant has responded to concerns and points of clarification raised by the Committee. Their response to the points listed in paragraph 2 is summarised below and the full response is attached (**Annex 7**).
 - i) The applicant acknowledges that bee venom does have the potential to cause severe allergic reactions in a small proportion of the population but states that normal honey and other bee products are also capable of this. The applicant states that in New Zealand, other bee products such as royal jelly, pollen or propolis cause more allergic reactions than honey products with bee venom.
 - ii) The applicant considers that wider use of bee venom in honey-based products may result in a reduction in allergic responses and notes that administration of bee venom is used as a method for desensitising people with a history of local and systemic reactions to bee stings.
 - iii) The applicant states that current knowledge of the exact mechanisms of action of sublingual (or oral/mucosal) immunotherapy is at a basic level and the mechanisms by which orally consumed bee venom confers immunological and anti-inflammatory benefits are also not fully understood. However, recent studies have shown that peptides from bee venom allergens can confer reduced immunological responses and the applicant has provided some examples in the response.
 - iv) The applicant states that honey (particularly Manuka honey) has been shown to reduce dental caries by inhibiting the growth of dental plaque bacteria, reducing the amount of acid produced and inhibiting bacterial dextran production. In relation to other types of honey (non-Manuka) with no antimicrobial activity, the applicant states that the suggested consumption of 2 teaspoons per day equates to approx. 16g carbohydrate which is close to the amount of sugar many people would consume in two cups of tea or coffee per day.
 - v) The applicant states that overall, the trial indicated a small improvement only in pain score and only in patients with osteoarthritis. The magnitude of the improvement lay within the expected placebo response range and may not be clinically significant. The study report discussed the possibility of a relatively high placebo response rate, though the cross-over design of the trial was used to try and mitigate this, and the possibility that placebo honey may also have contained a low level of bee venom. The applicant emphasises that the trial showed that Manuka honey with bee venom appears safe for patients who are not allergic to bee products.

**Secretariat
August 2009**

Annexes attached

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| ANNEX 5 | Letter of 4 August 2009 to the applicant with the Committee's comments |
| ANNEX 6 | Summary of public comments (excluding the 115 comments from customers of bee venom products) |
| ANNEX 7 | The applicant's response to the Committee's comments |

Annex 5 to ACNFP/94/1

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter of 4 August 2009 to the applicant with the Committee's comments

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Summary of public comments

(excluding 115 comments from customers of bee venom products)

**Summary of Public Comments received during 21 day consultation period
(excluding 115 comments from customers of bee venom products)**

<p>1) Concern was expressed relating to the welfare of bees as a result of the production of bee venom and confirmation was requested that no harm is afforded to bees during the production of bee venom.</p>
<p>2) Concern was expressed on the ethical aspect of the exploitation of honey bees stating that these organisms are already significantly under threat. In addition to this, the same individual expressed concerns that it is not possible to be fully aware of the possible effects of bee venom on the human body particularly if the novel ingredient is abused. Further concern was expressed on the possibility that animals may consume this ingredient as a result of food waste being improperly handled or human error and any consequent effects on the animals.</p>
<p>3) A further comment was received indicating that honey bees are under threat and need to be preserved for pollination processes essential to food production. In addition to this, the enquirer requested information on whether any research has been undertaken to support that bee venom is effective in alleviating arthritic symptoms and if so this needs to be considered before allowing this novel ingredient to be authorised.</p>
<p>4) A public comment was received advising against acceptance of this application given that allergy to bee stings is potentially life threatening. The commentator expresses that the human study to demonstrate safety and efficacy in the dossier did not indicate any long term follow up to determine whether allergic conditions had been induced. It was further stated that adverse reactions reports would not necessarily detect such an induction since the trigger for an allergic reaction might be temporally dissociated from the use of venom-treated honey.</p>
<p>5) A question was posed on the nature of the scientific research to support the benefits of bee venom. The enquirer's view was that if venom alleviates arthritic symptoms through its pharmacological properties, it may be more appropriate to classify venom as a novel drug rather than a novel food. The enquirer stated that bee venom is known to cause severe reactions to individuals via the skin or blood system and enquired whether evidence exists to suggest that use as a food may be safer.</p>
<p>6) A comment was received from an individual from Russia where venom is used in ointments for muscular pain and the individual states that bee venom is effective in treating such conditions.</p>
<p>7) A comment was received from an individual who had in the past received immunotherapy for bee venom allergy, although it is not clear in which Country this took place. The individual informed that her reaction to venom was measured as being reactive to one part bee venom to 10, 000 parts of saline solution. The individual states that approximately 3% of the population are unknowingly allergic to bee venom and is extremely concerned that consumption of honey with bee venom may have the potential</p>

to cause mortalities . The individual has requested that the Food Standards Agency takes advice from one of the UK immunotherapy/allergy centres such as Southampton General Hospital before agreeing to authorise this product.

8) A Trading Standards Officer expressed a number of concerns relating to honey with bee venom which are summarised below.

- a) The product will be marketed as a food that provides a health benefit and must be considered along with the Nutrition and Health Claims Regulation 1924/2006. If approval as a novel food were granted the claims would need to be included on the appropriate list under the above Regulation otherwise they would be prohibited health claims. The application is worded so as to imply that bee venom has a medicinal effect rather than a health benefit and does not appear to take Regulation 1924/2006 into account.
- b) Should bee venom be approved as a novel ingredient, it is important to consider whether the levels of this novel ingredient added to honey can be quantified to ensure that products are correctly described. Additionally, as honey naturally contains bee venom, easy and affordable quantifiable methods need to be considered to ensure that the naturally occurring and commercially added venom products are distinguishable to prevent possible food fraud.
- c) The viability of collecting bee venom on a commercial scale was questioned and it was suggested that the assessment should include site visits to observe collection, storage, measured application and quantifiable mixing of venom to the honey.
- d) The likelihood that the proposed low levels of bee venom will be absorbed through the gut to provide the suggested health benefits was questioned.
- e) It was highlighted that the high levels of sugar present in honey may conflict with the health benefits of this product.
- f) It was questioned whether honey with bee venom should continue to be on the UK market whilst the assessment is carried out. It was stated that an official statement from the FSA would be beneficial. ***[To note for background: Bee venom products were being distributed in the UK through a company NectarEase, which has subsequently advised the Agency that they will not distribute further honey with bee venom products in the UK until approval is granted.]***
- g) The UK initial assessment should not reflect the application in stating that bee venom can treat or cure arthritis as this will lead to confusion as to how the product can be marketed in the EU.
- h) Honey with bee venom will likely be far more expensive than standard honey products on the market so there is a need to be certain about why this product is being marketed. The assessment needs careful consideration along with appropriate scientific research undertaken with appropriate consumer groups.
- i) Currently, Manuka honey on the market has claims such as UMF 16+ (unique Manuka Factor 16+) and it is not certain how reliable these claims are or whether they can be substantiated. It is likely that the bee venom claim and the UMF claims will be linked in most cases.

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Annex 7 to ACNFP/94/1

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The applicant's response to the ACNFP's comments

**Secretariat
August 2009**