

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

KIWIBERRY CONCENTRATE

Issue

Following the discussion at the last meeting, the Committee is invited to consider additional comments from Members with expertise in food allergy, in order to determine whether the data provided by the applicant regarding the likely extent of allergenicity together with their proposed risk management strategy, is adequate to complete the risk assessment of this novel food ingredient.

Background

1. At the July 2007 meeting Members considered an application for the authorisation of kiwiberry concentrate from the hardy kiwi, (*Actinidia arguta*) as a novel food ingredient (NI) (ACNFP/83/5) for use in a range of food products.
2. During their initial consideration, Members highlighted a number of concerns predominantly in the area of allergy, and the applicant's response to these concerns was considered at the September meeting (ACNFP/84/4). At this meeting Members disagreed with the applicant's statement that kiwi allergy was not an issue of great concern in the UK, as allergy to kiwi fruit is becoming increasingly common in the UK and other European countries and people with this allergy can suffer life-threatening reactions. (The applicant has now indicated that their statement was a reflection of the incidence of kiwi allergy in the population as a whole and not individual cases).
3. At the July meeting, Members advised that the allergenicity studies carried out by the applicant were insufficient to complete the safety assessment of the NI, as they did not accurately reflect the likely extent of cross-reactivity amongst individuals who are currently allergic to green kiwi. The applicant has proposed that all products containing the NI are clearly labelled, to ensure that any individual who is allergic to green kiwi can avoid the NI.
4. In order that the safety assessment of the NI can be completed, the Secretariat has liaised directly with ACNFP allergy experts to determine what additional studies could be carried out to determine the true extent of allergenicity and Members raised the following points:
 - I do not think the allergenicity study was undertaken as part of a concerted effort to provide data for a novel foods application.
 - There are real problems in the preparation of kiwi fruit allergens and extracts to perform serological analysis of the type described by Chen et al¹ in a reproducible fashion - which is probably why only 2/11 sera reacted on blots. This is because of the

¹ Chen, L.; Lucas, J.S.; O'Hourihane, J.O.; Lindemann, J.; Taylor, S.L.; Goodman, R.E.; Food and Chemical Toxicology **44**, 1100-1107, (2006)

extremely high concentration of the protease actinidin in the flesh of the fruit. This means extracts prepared for serology (determining IgE binding by immunoassay of immunoblotting) and skin testing are not as effective as prick-to-prick or oral challenge. Immunoblotting is not the technique that is credible to assess the effects of processing on the allergens at all.

- Table 1 of the Chen et al paper includes oral challenge data but from my reading of the paper there were 4 individuals who had oral challenge done with both green and golden kiwi. No data are given on the quality of the blinding (nor how it was done) or the dose at which objective symptoms were obtained. Of these four individuals 3 reacted to both green and golden kiwi, one only to green. None were tested with processed kiwi. Skin prick testing (SPT) seems only to have been done with green kiwi. The best journals would require a much larger no of individuals to be challenged than this. For example, 30 subjects are required in order to establish thresholds for allergens so this is a pretty small panel, especially since there are three different types of kiwi allergy - kiwi alone, kiwi-birch pollen, kiwi-latex. Four is more an indication of likelihood....
 - Given the interest and importance of kiwi allergy in the UK we need objective information on which to base our advice. There is no published literature of the correct kind to provide us with this information and whilst the Chen et al paper is interesting it does not do this adequately. We need to see a study which shows in a more direct way in man the effect of processing on the allergenicity. I think this can only be done using SPT [at least] with prick-to-prick with kiwi fruits before and after processing in a panel of kiwi allergic individuals which covers the types of kiwi allergy you observe as in vitro methods do not work well with kiwi because of the problems in preparing allergen extracts.
 - It would be possible to treat the kiwiberry extract as being equal to kiwi fruit as generally eaten and just label. The acceptability of this solution is a decision for risk managers. My personal view is that because of the importance of kiwi allergy in the UK population this would be a superficial way to treat the matter.
 - My concern relates to the high and increasing frequency of kiwi fruit allergy and its involvement in some form of oral allergy syndrome. I would like to see stronger labelling and a larger number of serum samples tested to be clearer how often we might predict a reaction *in vivo*. A wider range of subjects includes those with the oral allergy syndrome.
 - While the remit of the ACNFP does not allow us to reject a product on the grounds that it might unreasonably restrict the choice of allergic patients, this should at least be raised as an issue. Maybe EFSA should address this as a generic problem.
 - However, there is a further risk which we must highlight as many food allergic patients take chances with processed foods. If they appear to tolerate a product which is indicated as containing their allergen they can wrongly assume that their allergy has resolved and put themselves at greater risk with the unmodified allergen. This is not just theoretical but has actually happened and has been discussed by members of the Anaphylaxis Campaign.
5. In order that these comments can be considered fully, the September ACNFP paper, including the applicant's response to Members concerns, is attached at **Annex 1**.

6. In discussions with the Secretariat, the applicant has reiterated their view that the proposed labelling criteria is sufficient to ensure adequate management of risk. They have also indicated that they have no plans to carry out any additional allergenicity studies, and have suggested that further data on cross-reactivity are unlikely to lead to different risk management decisions.

Committee Action Required

7. The Committee is asked to consider the comments listed above and to advise whether it is able to conclude its risk assessment of this novel ingredient, given that it is unlikely that the Committee will obtain further information that would help to address the uncertainties about the extent of cross-reactivity between the NI and existing allergens.
8. The Committee is also invited to provide any further comments on the effectiveness and implications of the risk management option proposed by the applicant, namely to highlight the presence of the novel ingredient where it is used in foods, and to include a statement advising against consumption by people with kiwi allergy. Other risk management options would include a more restrictive list of food categories and providing specific information to health professionals and allergy support groups.
9. Following this meeting, the Secretariat proposes to draft an opinion incorporating the Committee's comments on Efficas Inc's application, which will be discussed at the next Committee meeting in January.

**Secretariat
September 2007**

Annexes attached:

Annex 1 – paper ACNFP/84/4

ANNEX 1 to ACNFP/85/2

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Committee paper ACNFP/84/4

(September 2007)

**Secretariat
November 2007**