

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CHIA SEED

Issue

Members are invited to consider a draft opinion on this novel food application, which was previously discussed at Committee meetings in July 2003 and February 2004.

Background

1. At its February meeting, the Committee considered the applicant's responses to questions and concerns raised by Members when the application dossier was first discussed in July last year. While most of these issues had been answered satisfactorily, there were two outstanding issues: quality control systems applied during transport and storage and potential allergenicity.

Quality control

2. The Committee highlighted the need to control moisture levels during transport, and to establish suitable systems for monitoring the effectiveness of the HACCP system. The applicant has acknowledged that monitoring systems are an integral part of any HACCP system and has confirmed that monitoring will be undertaken when the product is authorised and imported for food use in the EU. The HACCP system will include the transportation stages. They have also pointed out that HACCP systems are subject to external audit and inspection which will provide an additional check that their system is effective and appropriate for the local conditions.

Potential allergenicity

3. An earlier study identified two individuals among a group of nut allergy sufferers who reacted to chia; these two individuals were also known to be allergic to sesame seeds. The applicant did not propose to undertake specific studies to determine the incidence of cross-reactivity between chia and sesame or other allergenic seeds such as mustard. Instead, the applicant suggested that foods containing chia (i.e. softgrain bread products) should be labelled as unsuitable for people with seed allergy.
4. The Committee accepted that this would minimise the risk, but were concerned that precautionary labelling would restrict the availability of products to allergy sufferers when there was no hard evidence that this restriction was justified. The Committee also noted that any bakery using chia seed might label many other products with "may contain" warnings if there was risk of accidental transfer of the ingredient between product lines, further restricting choice among allergy sufferers.

5. The applicant has pointed out that their application is for the use of chia in softgrain breads, which typically contain other grains and seeds. Such products may already use sesame seeds or other ingredients that render them unsuitable for seed allergy sufferers. Also, bakers who choose to use chia will invariably also be using sesame and other seeds in their recipes and it is unlikely that the use of chia in a bakery will result in an increased use of "may contain" labels compared with current practice.
6. The over-use of "may contain" labels has been criticised on many occasions on the grounds that it is unduly restrictive for people with allergies, who find that their choice of allergen-free foods is limited. This issue is being tackled by the Agency in the following ways:
 - The Agency is currently producing 'Best Practice' advice for caterers in relation to food allergy and this should be published in the next few months. It is possible that this advice could be extended to those selling loose foods such as bakery products. However, many people who are allergic to nuts and seeds do not purchase non-prepacked products from bakeries because of the risks of cross contamination.
 - The Agency has commissioned a report on the use of "may contain" phrases and a focus group study of consumer attitudes to such labelling. It has also held a meeting with stakeholders to discuss the report and the results of the focus group. The report shows that the labelling of products that may contain nut traces is not consistent and is often confusing and difficult to read and locate. The study showed that it would be helpful to allergic consumers to introduce clearer, more informative label statements where products might be contaminated with allergenic ingredients, like peanuts, nuts and sesame, which can cause severe reactions at low levels. The Agency is now consulting all interested parties on alternative phrases to be used in place of "may contain X" namely "Not suitable for peanut/nut/sesame allergic consumers" or "Not suitable for people with peanut/nut/sesame allergy". Following the consultation, the most appropriate alternative phrase will be inserted into the Agency's Clear Labelling Advice.
 - The Agency has a longer-term objective of introducing formal guidance on the use of 'May Contain' labels on prepacked foods.

Discussion

7. The purpose of the initial assessment under regulation 258/97 is to determine if the product meets the three criteria for novel foods and novel ingredients, as set out in Article 3(1) of the regulation. Namely, the product must not:
 - present a risk to the health of the consumer
 - mislead the consumer
 - be nutritionally disadvantageous compared with existing ingredients that it might replace.

8. The Committee has previously noted that other issues of importance to consumers, such as Access and Choice, are not part of these statutory criteria and has agreed that these issues should nevertheless be flagged up during the assessment process.
9. In the case of chia, the three essential criteria appear to have been met. Under the first point there is scientific uncertainty over the likely incidence of cross reactivity between chia and other seed allergens but this has been addressed in a precautionary manner by the applicant's labelling proposal.
10. The Secretariat has therefore drafted the attached initial opinion. The Committee's concerns over restriction of choice resulting from precautionary labelling do not represent grounds for refusing authorisation under the novel foods regulation. This is however a relevant issue and is highlighted in the Conclusions of the draft opinion.

Committee Action Required

11. The Committee is invited to consider the attached draft opinion and to suggest any amendments or additions.
12. Once Members' comments have been incorporated, the opinion will be published on the Agency web site for a short period of public consultation before being finalised and submitted to the European Commission as the basis for the formal UK opinion on hits application.

**Secretariat
February 2004**

Annexes:

attached:

Annex 1 – Draft Initial Opinion (restricted)

available on request:

[none]