

## ADVISORY COMMITTEE ON NOVEL FOOD AND PROCESSES

### Criteria for Assessing Substantial Equivalence of Novel Foods

#### Issue

Members are invited to consider draft guidance to applicants who wish to obtain an opinion from the Committee on the "equivalence" of novel foods or novel ingredients with existing counterparts, as part of the simplified authorisation procedure that is described in the novel foods regulation.

#### Background

1. The procedure for notification of novel foods based on the principle of "substantial equivalence" was described in the paper ACNFP/64/9 at the February meeting. That paper recommended the establishment of guidelines for the presentation of data to support an applicant's claims of equivalence between a new product and its existing counterpart. A first draft of such guidelines was presented, setting out the minimum criteria for judging substantial equivalence between novel and existing foods or food ingredients. Due to time constraints, the paper was not discussed in detail and Members were invited to provide any comments in writing.
2. A slightly revised version of the document is attached.

#### Committee action required

3. The Committee is invited to consider whether
  - it would be useful to develop guidance for applicants along the lines of the attached draft; and
  - if so, if they have any final comments on the text.

**Secretariat**  
**March 2004**

#### Annexes:

Attached: draft ACNFP guidance on substantial equivalence