

Scientific Advisory Committee on Nutrition

Paper for Information:

**Current Arrangements for the
Assessment of Nutritional Aspect
of Novel Foods**

**Agenda Item:
AOB**

At the last SACN meeting on 27 March '02, Members requested information on the arrangements for the nutritional assessment of novel foods. Please see enclosed for details.

Members are requested to note. Comments are welcome.

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Background Note on the Current Arrangements for the Assessment of Nutritional Aspect of Novel Foods

Novel Foods Regulation (EC) 258/97

1. Under the terms and conditions of the Novel Foods Regulation (EC) 258/97 novel foods, defined as foods that do not have a history of consumption within the EU prior to May 1997, are subject to a pre-market safety assessment. A novel food application is made to a single Member State in the first instance, who has 90 days to produce an initial opinion. This opinion is then passed to all other Member States who have a further 60 days to comment or offer reasoned objections. The FSA seeks advice from the ACNFP on all novel food issues, including all applications made under (EC) 258/97. The ACNFP's Agendas are forwarded to the SACN Secretariat and who can to attend any ACNFP meetings, if appropriate.

UK Novel Food Applications

2. In the first instance, scientists in the ACNFP Secretariat have discussions with companies wishing to submit an application. These discussions not only clarify the application procedure, ensuring that the applicant is aware of the SCF Submission Guidelines and the 'Decision Tree' to assist in the compilation of an application dossier, but also provide a means for the Secretariat to highlight any potential weaknesses in the application dossier. Such weaknesses can then be passed to colleagues in other divisions including Nutrition (via the SACN Secretariat) for comment and expert advice. In addition, the Secretariat can contact members of the ACNFP informally with such queries being directed to specific areas of expertise on the Committee. This happened with recent applications such as DHA-Gold and cholesterol lowering food ingredients, as well as a number of pipeline enquiries. After an application is formally accepted it is considered by the ACNFP and members can ask for additional specialist advice from other Committees before coming to a final decision.

Applications made to other Member States

3. The Initial Opinion from other Member States is discussed at an ACNFP meeting, or if there is no meeting scheduled within the 60 day period, member's comments are requested by post. In these cases, the Secretariat is reliant on the ACNFP nutrition experts for comment on any nutrition issues. However the advice of SACN could still be sought, although due to the short time-scales involved it is likely that these would have to be to individuals by post. Due to the time-scale restrictions, any areas of particular concern that cannot be resolved within the UK can be highlighted and objections made on these grounds, necessitating review of the application by the SCF.

Cross Representation

4. Although there are no *Ex Officio* Committee members of SACN on ACNFP or vice versa, the ACNFP Secretariat is aware that Professor Aggett sits on both Committees and will ensure that any Novel Food nutrition issues that are of relevance to SACN are forwarded to the Secretariat, to be tabled at a future meeting.
5. Following the establishment of the European Food Safety Authority, these arrangements may need to be changed if assessments are carried out centrally.