

## **Draft Minutes of the third meeting of the ANANF 20 November 2008, Conference Room 5.**

### **Present:**

#### Members

Alan Jackson –	SACN (Chair)
Anthony Williams -	SACN
Paul Haggerty –	SACN/ACNFP
John Mathers –	ACNFP
Gillian Pope -	ACNFP

#### Secreteriat

Sandy Lawrie –	FSA
Elaine Stone -	FSA
Chris Jones -	FSA
Heiko Stolte	FSA
Manisha Upadhyay (Minutes)	FSA

### **1. Apologies and Announcements**

Apologies were received from Mike Gasson.

### **2. Minutes of the second ANANF meeting.**

There were no comments on the minutes and these were agreed to be an accurate record of the last meeting.

### **3. Update on the work of the sub-group and recent developments**

The Secretariat introduced the information paper on the work of the SACN/ACNFP subgroup (ANANF/07) for the benefit of all new Members and highlighted that the subgroup was set up in 2004 to investigate ways to develop guidelines for nutritional assessment of novel and GM foods, which as they stand provide very little detail on what is required from the applicant.

The main development since the last ANANF meeting was that the European Food Safety Authority (EFSA) has published it's own guidelines for the nutritional assessment of foods from GM plants and GM microorganisms. EFSA's GMO panel has spent a considerable length of time discussing the role of animal feeding trials and in 2008, published a report on the role of animal feeding trials in the safety and nutritional assessment of GM plants and derived food and feed.

### **4. Discussion of draft guidelines for the nutritional assessment of Novel Foods.**

The Secretariat (SL) introduced the draft guidelines and mentioned that the structure and aim of the guidelines was explained to the subgroup at the last meeting. New sections on the scope of guidelines and a range of case studies as examples have been added into the guidelines..

There was a general discussion relating to consumer choice and risk management and members highlighted that it would not be desirable to have a situation where consumers were required to titrate their own intake of a particular ingredient. The importance of considering the range of likely intake levels was emphasised, giving the cases of vitamin A and folic acid as example. The Secretariat clarified that for novel foods there are very few cases where consumers are required to take responsibility for managing intake levels of a particular ingredient, with the only example being for phytosterols and that for new products, post-market monitoring may be required to confirm consumers actual levels of intake.

Members reviewed the revised draft guidelines section by section

Pg 4 , lines 69-70 it was suggested that the text “must not mislead the consumer” assumes that the consumer had some knowledge relating to a particular food, whereas this may not be the case. However, there was no alternative text proposed. It was acknowledged that the trend in the area of novel foods is moving towards health benefits rather than simply foods produced from different sources and that this could be reflected in the scope of the document.

## **Section 2**

Members discussed the issue of benefit versus risk. A member mentioned that from an ACNFP perspective, benefits to consumers are not assessed, only risk is assessed. He also pointed out that the current scope section does not offer a basis to balance risks against benefits. A member highlighted that when a food product is on the shelf, consumers expect that the product carries food like benefits and that the product is safe and stated that it was the committee’s task to provide the guidelines to ensure that this would be the case. The Secretariat stated that although novel ingredients are not assessed for efficacy, an awareness of the mechanism of action of a particular product is required in order that individuals that may not benefit from the product will be accounted for in terms of safety. A member mentioned the need to highlight to consumers the benefits of a particular food in simple language. It was also suggested that the Scope should include a simple sentence that acknowledges that the complexity of food in the diets.]

## **Section 3**

Relating to Section 3 (Pg 5-10), The Secretariat clarified to members that the reason for choosing the examples of foods/ingredients in the case studies presented in the guidelines document was because the examples were interesting and exemplified a range of different novel foods. A member stated that it would be useful to list which of the novel foods/ingredients on the list have been authorised and which ones have not

#### **Section 4**

There was a discussion on postmarket monitoring relating to adverse outcomes. Sandy mentioned there are processes in place (careline type systems) where individuals are able to comment on a product. Relating to allergenicity effects, awareness and data gathering are largely dependent on allergy clinics and consumer campaigns, there is no formal way of going about this. It was noted by Members that all these systems capture acute effects but not chronic or low grade effects. A member suggested a simple tool to facilitate postmarket monitoring would be to place a label on a particular product with a contact telephone number or webpage address that would allow consumers to easily provide comments on the product. A member suggested that different systems to detect adverse effects should be considered. and that some horizon scanning may be needed for different levels of protection]

The Secreteriat mentioned that if a product is likely to cause adverse effects, this needs to be addressed before authorisation but this approach assumes that we know everything about the product whereas this is not the case. Attendees agreed that if more postmarket monitoring was to be carried out, any data generated needs to be utilised properly and if adverse effects are observed, the risk assessment procedure could be repeated. It was agreed by all attendees that guidance on postmarket monitoring was not the function of this document but postmarket monitoring procedures do need more clarity and it would be helpful to applicants if more comprehensive guidance was available as a number of applicants would be willing to carry this out. It was mentioned that the ILSE guidelines on postmarket monitoring would provide useful reference.

#### **Section 5 – Nutritional assessment**

A member mentioned that relating to the information on existing guidelines for nutritional and GM foods, it is important to point out the broad and general nature of these guidelines.

There was a brief discussion on the new draft proposal to amend the Novel Foods Regulation in relation to the possibility that substances with no history of safe use in the EU but with a safe history of use in third countries could be assessed under the simplified procedure. It was highlighted by the group that not all populations are the same and will not react the same to a particular food.

5.3.1 Members proposed amendments to the bullet points in this section so that the points being made could be more clearly highlighted (see attached copy of draft guidelines). Members highlighted that the bullet points should confer the following three objectives, respectively. The first bullet point should be a statement about the total diet. The second bullet point should refer to who is likely to consume the product and the third bullet point should refer to who the product is intended for and who not intended for. Members were satisfied with the fourth bullet point.

## **AOB**

Sandy Lawrie to redraft draft guidelines document by middle of January 2009 and then send for comment to ANANF Members after which the draft will go to the main committees (ACNFP and SACN) for comment and then for public consultation. **[Action: Sandy Lawrie]**

A member suggested that it would be useful to have a SACN perspective on certain applications assessed by the ACNFP and this could be organised via the ACNFP/SACN secretariats **[Action: ACNFP secretariat to liaise with SACN secretariat and Members as appropriate].**