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BELGIUM

5<sup>th</sup> July 2002

Reference: NFU 194

Dear Dr. Tinland

**Request for Scientific Opinions on the Substantial Equivalence of Cottonseed Oil Derived from Genetically Modified lines.**

The UK Competent Authority took advice from the Advisory Committee on Novel Foods and Processes (ACNFP), and considered your applications under Articles 3(4) and 5 of the Novel Food Regulation, (EC) 258/97, on the substantial equivalence of oil derived from two distinct genetically modified cotton lines, Insect Protected line 531 and Roundup Ready line 1445. The Committee agreed that processed oils derived from these lines were equivalent, in composition, to oils from conventional cottonseed varieties. The scientific opinions of the ACNFP on these two oils are attached. The two opinions, together with this letter, will appear on the ACNFP pages of the Food Standards Agency website.

Although the ACNFP is content that the oils are substantially equivalent to their conventional counterparts, the Committee did have a number of comments on the presentational quality of the molecular biology characterisation data.

1) Members regarded the inclusion of Roundup Ready line 1698 as a control in many of the Southern blots to be misleading and unnecessary. The Committee was of the view that some of the information was confusing, and although the molecular biology experts on the ACNFP could understand the significant points, it was felt that the lay person would have some difficulties. Please be mindful of this point when making applications of this nature in the future.

2) As previously discussed, the explanation in the text describing the genetic components of plasmid PV-GHGT06, which is present in RRC line 1698, is not clear. The Committee recommends the following text be substituted for the penultimate sentence under section IV, part D. Characterisation of the insertion event:

“Plasmid PV-GHGT06 is a derivative of Plasmid PVGHGT07. PV-GHGT06 lacks a region of 2.492 kbp containing the entire *gox* gene cassette. This cassette contains a CmoVb promoter, a *ctp* chloroplast targeting region, a *gox* open reading frame and a NOS 3' termination signal.”

3) It was noted that several blots showed unequal intensity of signal and no explanation for this was given. Members felt that it would have been beneficial to see images of the original gels in order to demonstrate equal sample loading.

4) Members commented that the images in the original application were poorly labelled and unclear. The Committee accepts that many of the blots were carried out nearly 10 years ago, however, they felt that such standards would be unacceptable in an application submitted today. You may be aware that the Advisory Committee on Releases to the Environment is developing molecular data requirement guidelines, and in the future, you would be advised to submit data of the standard indicated in this document.

5) Members also wished it to be noted that they had concerns about the use of the *aad* marker gene in the transformation construct. However, since it has been demonstrated that there is no detectable DNA or protein in the oils, this is not a food safety issue. As you are aware, this gene confers resistance to the antibiotics spectinomycin and streptomycin. This is of particular concern since spectinomycin is sometimes used in the treatment of *Neisseria gonorrhoeae*. For further information on the ACNFP's opinion on the use of this marker gene, please look on the ACNFP pages of the FSA website, at the following address:

<http://www.food.gov.uk/science/ouradvisors/novelfood/acnfppapers/cottonseed>

However, despite the lack of clarity in some of the molecular data, the Committee agreed that, because it had been demonstrated that there was no detectable DNA present in the processed oils, this did not detract from the food safety assessment. Members are therefore content that the oils derived from the two GM cotton lines are equivalent in terms of composition to their counterparts derived from non-GM sources.

Yours sincerely

Sue Hattersley  
Novel Foods Division  
Food Standards Agency.