COMMITTEE PAPER – FOR DISCUSSION **ACNFP/94/5**

ADVISORY COMMITTEE ON NOVEL FOOD AND PROCESSES

EFSA OPINIONS ON ANTIBIOTIC RESISTANCE MARKER GENES

Issue

The Committee is invited to consider two recent opinions from the European Food Safety Authority regarding the use of antibiotic resistance marker genes in GM plants.

Background

1. In June 2009 EFSA published two scientific opinions relating to the use of antibiotic resistance marker genes in GM plants and the implications for human health and environmental safety.

2. These opinions were developed in response to a request from the European Commission for EFSA to update its earlier opinions from 2004 (or ARM genes in general) and 2007 (on the *nptII* gene).

Opinion on the use of ARM genes in genetically modified plants

3. The first opinion (**Annex A**) was prepared jointly by EFSA's Scientific Panels on Generically Modified Organisms (GMO) and on Biological Hazards (BIOHAZ). It focusses on the two specific ARM genes that are present in GM crops that have been the subject of applications for European authorisation, namely:

    - the *nptII* gene, which confers resistance to kanamycin and neomycin; and

    - the *aadA* gene, which confers resistance to streptomycin and spectinomycin.

4. The Panels reviewed the available evidence and also liaised with the European Medicines Evaluation Agency (EMEA) before arriving at a series of conclusions that can be summarised as follows:

    - transfer of ARM genes from plants to bacteria has not been demonstrated in the absence of sequence identity between the inserted DNA sequence and the host genome, either in natural conditions or in the laboratory

    - in general, DNA transfer between plants and bacteria occurs at a low frequency compared with transfer between bacteria

    - resistance to antibiotics relevant to existing ARM genes (kanamycin, neomycin and streptomycin) is widely found in bacterial populations

- the presence and use of antibiotic substances are key factors in trhe development and dissemination of antibiotic resistance genes in bacteria

- despite uncertainties in some of the data (related to e.g. sampling and the detection of ARM genes) the available information indicates that adverse effects on human health or the environment resulting from the transfer of ARM genes from GM plant plants are unlikely

5. The combined opinion was formally adopted by the two Panels in March 2009 and published in June 2009. In the case of the BIOHAZ Panel, two of its 21 members expressed reservations on the last of the conclusions, concerning the likelihood of adverse effects on health and the environment. Minority opinions from these members are included in the document at Appendix D (pages 80-82).

Opinion on the consequences for previous EFSA assessments of individual GM plants

6. The second opinion (**Annex A**) was prepared by EFSA's GMO Panel and considered whether, in the light of the joint opinion of the GMO and BIOHAZ Panels, it was necessary to update existing EFSA opinions GM plants containing the *nptII* gene::

- MON863 maize (including its hybrids with GM maize lines NK603 and MON810); and
- EH92-527-1 starch potato

7. The GMO Panel concluded that there is no need to change its existing opinions on these GM crops.

Committee action required

8. The Committee is invited to consider and comment on the attached EFSA opinions.

Secretariat
June 2009

Annexes attached:

Annex A: Scientific Opinion of the EFSA GMO and BIOHAZ Panels on Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants
The EFSA Journal (2009) 1043, 1-8
Publicly available from www.efsa.europa.eu

Annex B: Scientific Opinion of the EFSA GMO Panel on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants.
The EFSA Journal (2009) 1108, 1-8
Publicly available from www.efsa.europa.eu