

16 July 2007

Background note to Council vote on BASF potato: chronology of the antibiotic resistant genes controversy - adds detail to press release of 13 July 2007, online at:

<http://www.greenpeace.org/eu-unit/press-centre/press-releases2/EU-vote-on-GE-potato>

2001: EU law states that any antibiotic resistance marker genes (ARMGs) which may have adverse effects on human health and the environment should be phased out by the end of 2004 (1).

2004: April, Commission receives application for marketing of BASF potato for cultivation and use in food and feed.

2004: In a report on ARMGs (2), the European Food Safety Authority (EFSA) concludes that use of the gene inserted in the BASF potato, *nptII*, does not pose a risk to health or the environment. Its conclusion is based on the assumption that antibiotics kanamycin and neomycin, which are affected by this gene, have “no or only minor therapeutic relevance” (3).

2005: The World Health Organisation (WHO) classifies kanamycin and neomycin as “critically important” antibacterials (4) (5).

2007: February, the EU Commission requests an opinion from the European Medicines Agency (EMA). The Agency confirms the WHO position, stating that kanamycin and neomycin “cannot be classified as of no or only minor therapeutic relevance” (6).

2007: 16 July, Commission to ask member states to approve EU-wide cultivation of BASF potato containing *nptII* gene.

Questions:

When did EFSA acquire the power to ignore EU law on ARMGs?

Does EFSA stand by its 2004 conclusions on *nptII* (since contradicted by WHO and EMA)?

Why did the Commission ignore EMA advice?

Conclusions:

In light of the above, Greenpeace will ask the Commission to take EMA’s opinion into account and, additionally, to request an opinion from the Institut Pasteur in France, or other independent scientific institutions with expertise on antibiotic resistance.

Greenpeace is calling for an urgent review of EFSA’s role in the authorisation of GMOs.

Notes

(1) Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Article 4(2).

(2) Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants (Question N EFSA-Q-2003-109). See page 11. The EFSA Journal (2004) 48, 1-18

(3) In its opinion on the use of antibiotic resistance genes the EFSA states that the risk of gene transfer from a GM plant to bacteria "*should be viewed against [1.] the presence of antibiotic resistance genes in soil, plants, water and enteric bacteria... and [2.] the importance of specific antibiotics in therapeutic use*".

(4) World Health Organisation, Critically Important Antibacterial Agents for Human Medicine for Risk Management Strategies of Non-Human Use. Report of a WHO working group consultation, 15-18 February 2005, Canberra, Australia.

(5) The WHO has three categories to define the relevance of antimicrobials: "Critically important", "Highly important" and "Important".

(6) European Medicines Agency (EMA) - Committee for medicinal products for veterinary use and Committee for medicinal products for human use, Presence of the antibiotic resistance marker gene *nptII* in GM plants for food and feed uses. EMA/CVMP/56937/2007. 22 February 2007.

(7) Statement of the Scientific Panel on Genetically Modified Organisms on the safe use of the *nptII* antibiotic resistance marker gene in genetically modified plants, adopted on 22-23 March 2007.

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