

**Summary of the opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-25 and EFSA-GMO-RX-T45) for the placing on the market of the glufosinate-tolerant genetically modified oilseed rape T45, for food and feed uses, import and processing and for renewal of the authorisation of oilseed rape T45 as existing product, both under Regulation (EC) No 1829/2003 from Bayer CropScience<sup>1</sup>**

**(Questions No EFSA-Q-2005-278 and EFSA-Q-2007-154)**

**Adopted on 30 January 2008**

## **SUMMARY**

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified oilseed rape T45 (Unique Identifier ACS-BNØØ8-2) developed to provide tolerance to glufosinate-ammonium herbicides.

In delivering its scientific opinion, the GMO Panel considered the new application EFSA-GMO-UK-2005-25, additional information provided by the applicant (Bayer CropScience) and the scientific comments submitted by the Member States. The scope of application EFSA-GMO-UK-2005-25 is for food and feed uses, import and processing of oilseed rape T45 and all derived products, but excluding cultivation of the crop in the EU. Information provided in the context of the application for renewal of the authorisation of oilseed rape T45 as existing product, submitted under Regulation (EC) No 1829/2003 (Reference EFSA-GMO-RX-T45), was also taken into account. The scope of application EFSA-GMO-RX-T45 covers the continued marketing of existing food additives and feed materials produced from oilseed rape T45.

A single risk assessment for all intended uses of genetically modified oilseed rape T45 has been performed by the GMO Panel and one single scientific opinion for both applications submitted under Regulation (EC) No 1829/2003 is issued. The GMO Panel assessed oilseed rape T45 with reference to the intended uses and the appropriate principles described in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006). The scientific assessment included molecular characterization of the inserted DNA and expression of the new protein. A comparative analysis of agronomic traits and composition was undertaken and the safety of the newly expressed protein and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.

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<sup>1</sup> For citation purposes: Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2005-25) for the placing on the market of glufosinate-tolerant oilseed rape T45 for food and feed uses, import and processing and renewal of the authorisation of oilseed rape T45 as existing products, both under Regulation (EC) 1829/2003 from Bayer CropScience, *The EFSA Journal* (2008) 635, 1-22.

Oilseed rape T45 was transformed by *Agrobacterium tumefaciens*-mediated gene transfer technology. Oilseed rape T45 expresses the *pat* gene leading to the production of the enzyme phosphinothricin acetyltransferase (PAT) that acetylates L-glufosinate-ammonium. The PAT enzyme confers tolerance to glufosinate-ammonium herbicides (trade names: Liberty®, Ignite®, Finale®, Basta®).

The molecular characterisation data established that only one copy of the gene cassette (corresponding to the T-DNA region of plasmid pHOE4/Ac(II)) is integrated in the oilseed rape genomic DNA. Appropriate analyses of the integration site including sequence determination of the inserted DNA and flanking regions and bioinformatic analysis have been performed. Bioinformatic analysis of junction regions demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The expression of the genes introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations.

The GMO Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of oilseed rape T45 does not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided.

Analyses carried out on materials from T45 oilseed rape and its non-GM comparators in a representative range of environments and seasons do not provide indication of biologically relevant compositional and agronomical changes. The GMO Panel is of the opinion that the composition of oilseed rape T45 does not deviate from that of conventional oilseed rape varieties, except for the introduced trait.

The PAT protein induced no adverse effects in acute dose oral toxicity studies in rodents. In addition, the PAT protein is rapidly degraded in simulated gastric fluid and inactivated during heat treatments.

A 42-day feeding study with broilers did not indicate differences in the nutritional value of T45 oilseed rape versus the non-GM comparator and confirms the nutritional equivalence of T45 oilseed rape containing diet in comparison with a conventional diet in broiler chickens.

The applications for oilseed rape T45 concern food and feed uses, import and processing of oilseed rape T45 and all derived products, but excluding cultivation of the crop in the EU. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of oilseed rape T45. There are no indications of increased likelihood of establishment or survival of feral oilseed rape plants in case of accidental release into the environment of oilseed rape T45 seeds during transportation and processing. The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of oilseed rape T45 since cultivation is excluded. The monitoring plan provided by the applicant is in line with the EFSA Guidance document (EFSA, 2006) and the Opinion of the GMO Panel on post-market environmental monitoring (EFSA, 2006). However, the GMO Panel advises that appropriate management systems should be in place to minimise accidental loss and spillage of transgenic oilseed rape during transportation, storage, handling in the environment and processing into derived products.

In conclusion, the GMO Panel considers that the information available for oilseed rape T45 addresses the scientific comments raised by the Member States and that the GM oilseed rape T45 is as safe as its non genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that oilseed rape T45 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.

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The Panel advises that appropriate management systems are in place to minimize accidental loss and spillage of transgenic oilseed rape during transportation, storage and handling in the environment and processing into derived products.

**Key words:** GMO, *Brassica napus*, oilseed rape, T45, glufosinate-ammonium herbicide, glufosinate-tolerant, *pat* gene, PAT protein, ACS-BNØØ8-2, human and animal health, environment, import, processing, Regulation (EC) No 1829/2003, renewal, existing product.