Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

1998/0072(COD) - 13/06/2007 - Follow-up document

The Commission has presented a proposal for a Council Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

In accordance with Directive 2001/18/EC, the Swedish authorities received from BASF Plant Science a notification (Reference C/SE/96/35-01) concerning the placing on the market of a potato (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch. In accordance with the Directive, the Swedish competent authority forwarded to the Commission its assessment report of the notification, which concluded that genetically modified potato should be placed on the market for its intended uses.

On 9 December 2005, BASF Plant Science informed the Swedish competent authority of its intention to exclude feed uses from the notification under Directive 2001/18/EC, limiting its scope to cultivation and production of starch for industrial uses. The Commission forwarded the assessment report to all other Member States, some of which raised and maintained objections to the placing on the market of the products in terms of molecular characterisation, allergenicity, toxicity, an inadequate monitoring plan and the detection method of the product.

In light of these objections, the Commission consulted with the European Food Safety Authority (EFSA), which delivered its opinion on 24 February 2006 concluding that, from all evidence provided, the genetically modified potato (Solanum tuberosum L. line EH92-527-1) is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

A draft of the measures to be taken was submitted for opinion to the Committee set up in accordance with Article 30 of Directive 2001/18/EC. The Committee which was consulted on 4 December 2006 has not delivered an opinion. Therefore, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament; the European Parliament was informed on 8 December 2006. The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

On 26 February 2007, in the light of a report published by the World Health Organisation listing kanamycin and neomycin as 'critically important antibacterial agents for human medicine and for risk management strategies of non-human use', the European Medicines Agency issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine.

On 23 March 2007, taking into account this statement, EFSA confirmed its previous assessment of the safe use of the antibiotic resistance marker gene nptII in genetically modified organisms and their derived products for food and feed uses. Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority on the proposal within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it; whereas if, on expiry of that period, the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

A number of strict conditions are included in the proposal. The specified conditions include the following requirements:

- the consent will be valid for a period of ten years starting from the date at which the consent is issued;
- the unique identifies of the products are BPS-25271-9;
- the consent holder provides positive and negative control samples of the product and its genetic material and reference material to the competent authorities;
- a detection method specific to the modified potato is made available, which has to be validated by the Community Reference Laboratory;
- the product is adequately labelled in accordance with EU provisions;
- operators and users are informed on the safety and general characteristics of the product;
- in view of the fact that the Decision covers only cultivation and industrial use, BASF Plant Sciences is obliged to ensure that the modified potato is: i) physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling ii) that they are delivered exclusively to designated starch processing plants for processing into industrial starch, avoiding any co-mingling with material derived from potatoes intended for food or feed; and iii) only processed into industrial starch. Any by products from the process should be used exclusively for industrial purposes or destroyed.

Strict monitoring conditions have also been set out including, inter alia, monitoring for any adverse effects on human and animal health or adverse effects on the environment, the submission of annual reports and the preparation of a monitoring plan.