

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

1998/0072(COD) - 18/11/2008 - Follow-up document

The Commission presents a proposal regarding giving consent to the placing on the market, in accordance with Directive 2001/18/EC of a carnation genetically modified for flower colour. In accordance with Article 13 of Directive 2001/18/EC, the Dutch authorities received in October 2006 by Florigene Ltd, Melbourne, Australia, a notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line 123.8.12). The notification covers import, distribution and retailing of *Dianthus caryophyllus* L., line 123.8.12 as for any other carnation.

In accordance with the procedure provided for in Article 14 of the Directive, the Dutch competent authority prepared an assessment report, which concluded that the genetically modified carnation (*Dianthus caryophyllus* L., line 123.8.12) should be placed on the market for import, distribution and retailing as for any other carnation.

The Commission forwarded the assessment report to all other Member States some of whom raised and maintained objections to the placing on the market of the products in terms of monitoring plan, allergenicity and toxicity, and detection of the product.

In light of these objections, the European Food Safety Authority (EFSA) was consulted and delivered its opinion in March 2008 concluding, from all evidence provided, that cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 123.8.12) are unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed ornamental use. The EFSA also found that the scope of the monitoring plan provided by the consent holder is in line with the intended use of the carnation.

The Commission, in accordance with Article 18 of Directive 2001/18/EC, is required to take a decision in accordance with the procedure laid down in Article 30(2) of the Directive to which Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

A draft of the measures to be taken was submitted in accordance with the relevant comitology procedure. The Committee, consulted on 15 September 2008, has not delivered an opinion, which requires that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament. The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

Article 5(6) of 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. 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.