

Brussels, 21 DEC. 2010
C/2010/ 92 01

Dear President,

The Commission would like to thank the Italian Senate for its analysis of the Commission proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory {COM(2010)375}.

The Commission shares the opinion of the Italian Senate that the proposal in question complies with the principles of subsidiarity and proportionality. In particular, the Commission agrees with the Italian Senate that Member States may be in a more appropriate position than the Commission to carry out their own impact assessments to justify their decisions about cultivation of GMOs in their territories at national, regional and local levels.

The Commission takes note of the firm belief of the Senate that Italy wishes to make use of the right provided for by the proposal in question to prohibit the cultivation of GMOs in their territory. The Commission wants to underline that this right will only be granted to Member States once the proposal is adopted through the ongoing co-decision procedure with Council and Parliament and subsequently enters into force.

As regards the substance of the proposal, the Commission has carefully noted the serious concerns of the Senate about the decision to exclude the possibility for individual Member States also to consider aspects relating to health and the environment. In fact, under the existing legal framework, Member States have the possibility to invoke the special procedures of the safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) in case they have serious grounds to consider that the authorised product is likely to constitute a serious risk to health and environment. Consequently, the Commission proposal stipulates that Member States cannot invoke protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures. This condition aims at preserving the authorisation system based on science set in the EU legislation.

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Like the Italian Senate, the Commission believes that GMOs need to be assessed in line with the precautionary principle enshrined in the existing EU legislation. Under this set of legislation, GMOs shall undergo an individual risk assessment before being authorised to be placed on the EU market.

The aim of this authorisation procedure is to ensure a high level of protection of human and animal health and the environment, whilst ensuring the effective functioning of the internal market. To maintain this high level of protection, Member States' measures under the current proposal cannot be based on grounds related to the assessment of the adverse effects on health and environment which are already addressed by the harmonised set of EU rules.

The Commission remains available to provide any further information on these issues if needed.

Yours sincerely,