

Brussels, 5/01/2011
C/2010/9331

Dear Ms Zissi,

The Commission would like to thank the Hellenic Parliament for its opinion on 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 welcomes the opinion of the Hellenic Parliament that the proposal in question complies with the principles of subsidiarity and proportionality. The Commission agrees with the Hellenic Parliament on the importance of preventing potential adverse effects of GMOs on human and animal health and the environment including in the long term, which is a fundamental objective of the current EU authorisation system. To maintain this high level of protection, the adverse effects on health and environment are already addressed by the harmonised set of EU rules, and are thus not included as possible grounds under the current proposal.

Indeed, under existing legislation, GMOs shall undergo an individual risk assessment before being authorised to be placed on the EU market including aspects relating to health and the environment. It is important to underline that Member States play a significant role in the authorisation procedure. Indeed, it is a Member State who carries out the initial assessment of GMOs for cultivation. Moreover, in the context of the implementation of the 2008 Council Conclusions on GMOs, additional Member States are invited to collaborate in this initial assessment with the lead Member State to make better use of European wide expertise. Member States should submit any data they may have which is relevant for the risk assessment.

The Commission has carefully noted the concerns of the Hellenic Parliament about the exclusion of aspects relating to health and environment as possible grounds for restricting or prohibiting GMO cultivation. 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.

The Commission takes note of the concerns of the Greek citizens as regards GMOs and wants to underline that the right provided for by the proposal to restrict or prohibit the cultivation

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of GMOs in their territory will be granted to Member States as soon as the proposal is adopted through the ongoing co-decision procedure with Council and Parliament and subsequently enters into force.

In connection with the natural and agronomic particularities of the Greek territory that the opinion of the Hellenic Parliament raises, the Commission notes firstly that it is possible in principle to differentiate between regions in the risk assessment, on the basis of scientific arguments¹. If the risk assessment concludes that the cultivation of a GMO raises particular regional concerns, these concerns must be addressed in the EU authorisation through specific conditions or risk management measures. Such measures may include restriction or prohibition measures, if scientifically justified. Secondly, when it comes to co-existence of GMOs with conventional and organic crops in Greece, the Recommendation on co-existence adopted on 13 July 2010 refers to the possibility for Member States to restrict GMO cultivation from certain areas of their territory to avoid the unintended presence of GMOs on conventional and organic crops. This has to rest on the demonstration that for those areas other measures are not sufficient. Moreover, Member States should ensure cross-border co-operation with neighbouring countries to guarantee the effective functioning of co-existence measures in border areas.

Regarding the question of the Hellenic Parliament about whether the proposal will give room for massive authorisations of GMO cultivation by the EU, it is important to underline that the proposal does not modify EU authorisation procedure as such. The Commission's proposal responds to a demand by 13 Member States², who called on the Commission to prepare proposals to give freedom to Member States to decide on cultivation of GMOs.

Finally, it should also be underlined that the proposal concerns the freedom of Member States to restrict or prohibit the act of cultivation of GM varieties but not the free marketing of authorised GM seeds throughout the EU or imports of such seeds from third countries once they have been authorised at EU level.

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

Yours faithfully,

/-/ Maroš Šefčovič

¹ In line with Article 19(3)(c) and Annex II of Directive 2001/18/EC and Article 6 and 18 of Regulation (EC) No 1829/2003.

² AT, BG, IE, EL, CY, LV, HU, LU, MT, NL, PL and SI.