

EUROPEAN COMMISSION

*Brussels, 9.7.2015
C(2015) 4629 final*

*Sir William CASH, MP
Chairman of the European
Scrutiny Committee
House of Commons
Palace of Westminster
UK - LONDON SW1A 0AA*

Dear Chairman,

The Commission would like to thank the House of Commons for its Opinion on "Advanced genetic techniques for crop improvement: regulation, risk and precaution".

On the question of whether the EU regulatory process fits its purpose, the Commission would like to draw the House of Commons' attention to two independent reports evaluating the European Union's legislation on Genetically Modified Organisms (GMOs) in 2010¹ and 2011². They found a broad support from the stakeholders for the legislation's objectives and pointed out that only some adjustments were necessary to meet the objectives of the legislation and to ensure its proper implementation.

The Commission has addressed the evaluation's recommendations, amongst others by amending Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001³, the work on co-existence and the study on "GMO-free labelling". The Commission considers that the current system, based on an EU-wide authorisation upon a favourable scientific opinion, addresses the safety objectives of the EU legislation. The Commission does not foresee a change in this basic principle.

¹ Evaluation of the EU legislative framework in the field of GM food and feed, Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain Final Report, July 2010 http://ec.europa.eu/food/plant/docs/plant_gmo_report_studies_evaluation_gm_report_en.pdf

² Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC, Final Report EPEC for DG SANCO, European Commission, Main Report March 2011, European Policy http://ec.europa.eu/food/plant/docs/plant_gmo_report_studies_gmo_cultivation_report_en.pdf

³ Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory Text with EEA relevance, Official Journal of the EU L 68, 13 March 2015, pp. 1–8.

The Commission endeavours to observe the 3-month deadline for food and feed authorisations, bearing in mind that it must engage in a series of steps and procedures before submitting a draft Decision to the Member States. New scientific information or concerns of Member States can lengthen this period.

Concerning the conclusion that the current EU system on GMOs fails to observe the principle of subsidiarity, the Commission would like to point out to the recently adopted amendment of Directive 2001/18/EC (Directive (EU) 2015/412), allowing Member States to restrict or ban cultivation on their territory. This amendment retains a strong EU risk assessment and authorisation system for GMOs, while at the same time giving Member States extended prerogatives to decide on GMO cultivation. This is a positive step towards the alignment of the legislation with citizens' expectations, while respecting the rights of all parties.

In addition, based on the Political Guidelines on which it was appointed, the Commission has recently concluded the review of the authorisation process for GM food and feed in the EU and proposed changes to the legislation⁴ allowing Member States to opt out from the use of a GM food or feed, in coherence with the model of Directive (EU) 2015/412. This proposal is another important step in bringing more subsidiarity in the EU system on GMOs.

As to the evaluation of costs and benefits, the Commission would like to point out that although not being considered in the EU decision-making process on individual GMO events, socio-economic impacts of GMOs are analysed, as also explained during the evidence session. Indeed Directive 2001/18/EC requires information to be gathered on socio-economic impacts of GMO cultivation, and such impacts might be part of the elements invoked by Member States to justify opting out from GMO cultivation under Regulation (EU) 2015/412. In 2013 the Commission set up a European GMO Socio-Economic Bureau, where experts from Member States are defining common science-based indicators to objectively measure the impacts of cultivation and use of GMOs in the EU. The Bureau is finalising a first general methodological document and subsequent reference documents will set indicators for socio-economic impacts per crop/trait at country/EU level.

On the question of the new plant breeding techniques, the Commission is currently working on a legal analysis to clarify which of these techniques fall under the definition of GMO in the Directive. The Commission expects to be in a position to present the results of its assessment by the end of 2015.

Regarding the precautionary principle, the Commission would like to stress that the precautionary principle is a cornerstone of EU legislation in general, and of the EU GMO legislation in particular. The risk assessment/risk management approach translates this principle into practice, in particular via the pre-market authorisation system based on risk assessment and risk management including monitoring of the effects of the released GMOs and possible risk mitigation measures or the possibility to amend or terminate the consent of a GMO based on the findings. Systematic review of new scientific data and monitoring obligations for authorised GMOs ensure that appropriate

⁴ COM(2015)176 and 177 final.

safety measures are taken if new risks arise. As explained during the hearing, the Commission has never used the precautionary principle to ban a GMO.


As regards Other Legitimate Factors (OLF), Regulation (EC) No 1829/2003 allows the Commission to take them into account in addition to the risks assessment carried out by EFSA. However, it has never been possible to identify an OLF justifying an EU-wide ban on products considered safe by EFSA.

The Commission hopes that these clarifications address the issues raised by the House of Commons and looks forward to continuing our political dialogue in the future.

Yours faithfully,

A handwritten signature in black ink, consisting of a large, stylized 'F' followed by 'Timmermans'.

*Frans Timmermans
First Vice-President*

A handwritten signature in black ink, starting with a large, circular flourish followed by 'Andriukaitis'.

*Vytenis Andriukaitis
Member of the Commission*