

# Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at [e.bonadio@abertay.ac.uk](mailto:e.bonadio@abertay.ac.uk)

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## Biotechnology

*This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.*

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### Recent Developments in EU Biotech Regulation: A Possible Solution to the Deadlock on Authorizations of GM Crops?

Vessela Hristova\*

The regulation of agricultural biotechnology in the European Union (EU) has become one of its most contested policies and a notorious example of a malfunctioning regulatory regime. In particular, the pre-market authorization of genetically modified organisms (GMOs) has been a tortuous process marked by delays and uncertainties. Typically, final authorization decisions are left to the European Commission after the endemic failures of the Regulatory Committee, and subsequently the Council, to reach a qualified majority for or against Commission

proposals. The stalemate is especially acute with regard to the authorization of GMOs for cultivation purposes with the last authorizations of GM crops dating back to 1998.

In light of this situation, the Commission decision of 2 March 2010, which sanctioned for the first time in twelve years the cultivation of a genetically modified plant in the EU (the starch potato Amflora), signals the Commission's determination to resolve the deadlock. The decision was accompanied by an announcement promising more freedom for Member States to determine whether or not to cultivate GM crops on their own territory.

The Amflora potato, genetically modified to produce higher starch content, is authorized to be cultivated for industrial purposes, such as paper production, while its by-products are authorized for use in animal feed. The German chemical company BASF, developer of the GM starch potato, launched the authorization request back in 2003. The favorable Commission decision came in March 2010, one month after the second Barroso Commission stepped into office and after both the Regulatory Committee and the Council failed to reach a qualified majority either for or against the authorization. The decision also marks the end of a series of exchanges between the Commission (requesting additional scientific opinions on the safety of the GM potato) and the European Food Safety Authority, the Union's independent scientific agency in charge of risk assessment. One of the scientifically controversial points lay in the possible health implications deriving from the presence of anti-resistant marker genes in the GM crop.

While the cultivation of the Amflora potato is expected to commence in Germany, the Czech Republic, Sweden and the Netherlands, other EU Member States have given less than a welcome to the authorization decision. Some countries, such as Austria and Italy, have indicated their intention to put in place national bans on cultivation of the Amflora potato.

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Simultaneously with the authorization decision, the Commission announced its plan to develop by the summer a proposal allowing Member States more freedom to decide whether or not to cultivate GMOs on their territory. This development follows a declaration by Jose Manuel Barroso made in the run-up to his nomination for a second term as President of the European Commission. In his "Political Guidelines for the Next Commission", he stated the intention of the Commission to introduce some changes in the framework to the effect that a Community authorization system based on science would be combined with granting greater freedom to Member States to decide whether or not they wish to cultivate GM crops on their territory.

The Commission compromise affording more flexibility in the GMO authorization framework comes after months of pressure from national governments. In specific terms, at the Environmental Council of March 2009, the Netherlands introduced a declaration proposing that Member States should have the right to decide unilaterally on issues of GMO cultivation. This initiative was taken up and further developed by Austria in the subsequent Council meeting of June 2009. It proposed an amendment to the regulatory framework in the form of an opt-out clause giving Member States the right to prohibit indefinitely the cultivation of GMOs on their territory. The Austrian declaration was officially supported by ten other Member States. It is worth noting that Austria and the Netherlands both advocate what would in effect be a devolution of competences to the national level but for very different reasons as they stand at the opposite ends of the spectrum with regard to GMOs. The Netherlands has traditionally supported genetic engineering and is dissatisfied with the slow EU regulatory process impeding its progress in this field. On the other hand, Austria – of all EU countries perhaps the most skeptical towards GM technology – supports devolution so that it can ban the cultivation of GMOs on its territory.

At the moment the European Commission is also working on a separate reform initiative meant to broaden the scope of concerns to be taken into consideration during the risk management phase. In December 2008, the Environment Council unanimously supported a declaration attached to its Council Conclusions that called for a strengthened environmental risk assessment, greater freedom for Member States to decide on GM-free zones, and an appraisal of socio-economic benefits and risks. Fol-

lowing this Council mandate, the European Commission launched a consultation procedure soliciting input from Member States on what they consider to be socio-economic aspects that should be taken into account when authorizing GMOs. With the deadline for national submissions now over, Member States are currently awaiting the results of the consultation, which should produce a preliminary proposal of a possible common definition of what socio-economic considerations entail. This initiative reveals pressure being exerted by Member States to go beyond scientific risk analysis for taking authorization decisions.

With the authorization of the Amflora potato, the second Barroso Commission has demonstrated a resolve to find solutions to the regulatory deadlock on GMO authorizations. The decision to move forward with authorizations of GM crops for cultivation is counterbalanced by the greater freedom afforded to Member States to decide whether to ban the cultivation on their own territory. While the Amflora potato is being cleared for planting in this spring season, the exact legal parameters of the compromise promising more flexibility for EU countries remain to be unveiled at the next Council meeting in June 2010.

## The first GMO Case in Front of the US Supreme Court: To Lift or Not to Lift the Alfalfa Planting Ban?

*Alberto Alemanno\**

Alfalfa is one of the most important legumes used in agriculture and the fourth most cultivated plant behind corn, soybeans and wheat in the US<sup>1</sup>. It has been grown in almost all federal states, occupies 9 million hectares and is primarily used in feed for dairy cows and beef cattle. US consumers also eat GM alfalfa as sprouts in salads and other foods. Roundup Ready alfalfa was developed by the agrobiotechnology firms Monsanto and Forage Genetics. It was originally approved in June 2005 for commercial sale by the US Department of Agriculture

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1 Alfalfa is a flowering plant which belongs to the pea family *Fabaceae* cultivated as an important forage crop. It is also widely known as lucerne and as lucerne grass in south Asia. It resembles clover with clusters of small purple flowers.