Genetically Modified Organisms (GMOs): The authorisation process for cultivation

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Introduction

GMOs are authorised for cultivation at European Union (EU) level following an application by a company. The legislative process involves several stages including scientific risk assessment, public consultation and a final decision where Member States may approve or reject the European Commission's (the Commission) proposal by qualified majority.

The Welsh Government has devolved competence over GMO policy in Wales but is required to act in accordance with European legislation. As the Member State, the UK is responsible for representing Wales on this issue at an EU level. Therefore if the Welsh Government wished to ban the cultivation of an EU crop in Wales it would need to do so through the UK.

In many cases to date Member States have failed to reach a qualified majority with a clear split emerging within the Council. In this instance the Commission may grant authorisation provided that a positive opinion is reached after the completion of a risk assessment. The split between Member States has led to long delays in the decision making process.

In 2010 the Commission set out a proposal for a Regulation to revise the current authorisation system and the reoccurring 'stalemate' between countries. The proposal stalled following concern from Member States but has recently been re-visited following complications surrounding the authorisation of maize 1507. The aim of the proposals is to grant Member States more flexibility to restrict or prohibit GMO cultivation based on ethical and moral criteria as well as scientific.

This Research Note provides a summary of the current process and the proposals for change.

The current authorisation process

GMOs are authorised for cultivation at EU level following an application by a company with the resulting decision applying to all EU countries. Applications can be submitted under **Regulation (EC) N° 1829/2003**[1] on Genetically Modified (GM) food and feed or under **Directive 2001/18/EC**[2] for the deliberate release of GMOs into the environment.

Risk Assessment

Following an application under Regulation 1829/2003 the **European Food Safety Agency (EFSA)**[3] assesses associated risks to the environment, human health and animal safety. In the case of cultivation the EFSA delegates the environmental risk assessment to a Member State which sends EFSA its risk assessment report. Normally the EFSA performs its assessment within 6 months of the application and issues a scientific opinion published in the **EFSA Journal**[4]. EFSA submits its opinion to the Commission and to EU countries.

The procedure is slightly different under Directive 2001/18. Companies must apply to the competent authority of the EU country where the GMO will be initially marketed. That country prepares an assessment report within 90 days. If another EU country reasonably objects to the assessment report the application is sent to the EFSA.

[1] Regulation (EC) N° 1829/2003 [accessed 14 February 2014]
[2] Directive 2001/18/EC [accessed 14 February 2014]
[3] EFSA [accessed 14 February 2014]
[4] EFSA Journal [accessed 14 February 2014]

Public Consultation

The EFSA makes the application summary available to the public, except for confidential aspects. Once published the public may comment (for 30 days) on the Commission website[5] for applications under Regulation 1829/2003, and on the Joint Research Centre website[6] on the assessment report by the 'lead' EU country under Directive 2001/18.

Final Decision

Within 3 months of receiving EFSA's opinion the Commission should grant or refuse the authorisation. Representatives of Member States approve the Commission's proposal by qualified majority in:

- The **Standing Committee on the Food Chain and Animal Health (SCoFAH)**[7] if the application was submitted under Regulation 1829/2003;
- The **Regulatory Committee under Directive 2001/18/EC** if the application was submitted under Directive 2001/18.

The proposal is adopted if either Committee approves it. If there is no opinion, the Commission may summon an **Appeal Committee** where EU countries can adopt/reject the proposal. If the Appeal Committee makes no decision, the Commission may adopt the proposal. [8] Authorisations are valid for 10 years and are renewable.

[5] European Commission **Public consultations on GM food & feed authorisation applications under Regulation 1829/2003** [accessed 19 February 2014]
[6] Joint Research Centre **Deliberate Release and Placing on the EU Market of GMOs - GMO Register** [accessed 14 February 2014]
[7] European Commission **The Standing Committee on the Food Chain and Animal Health** [accessed 14 February 2014]
[8] Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (**OJ L 184, 17.7.1999, p. 23**)

The 'safeguard clause'

- **Article 23 of the Directive 2001/18**, the 'safeguard clause', allows Member States to restrict or prohibit the cultivation or use of an authorised GMO product if they have new or additional scientific evidence that proves the product is a danger to the environment and/or human health within their territory. In order to prove that there is sufficient evidence the Member State must undertake a review of the original environmental risk assessment that was completed when the GMO was first consented. To assess the scientific merit of the claims the Commission may submit the Member State's evidence to the EFSA who will provide an opinion on the validity of the new evidence. Having received a scientific opinion from the EFSA the Commission will submit draft proposals to the SCoFAH calling for the Committee to either agree with the Member State's prohibition or to repeal the ban. The Committee will vote to adopt or reject the Commission's proposals. If the Committee fails to reach a decision the proposals will go to the **Council of Ministers** (the Council) for a decision. If the Council fails to respond to the proposals within a set timeframe the Commission will adopt the proposal.[9]

Maize 1507

On 26 September 2013, the **General Court of the European Union** delivered a ruling finding that the Commission failed to act on an application by **Pioneer** (now 'DuPont Pioneer') for the authorisation of **maize 1507**[10] for cultivation submitted in 2001 under the Directive 2001/18.

Pioneer initiated a first action against the Commission in 2007 for failing to present a decision of authorisation for voting to the Regulatory

[9] The decision making procedure is set out in **Article 5 of Decision 1995/486/EC** [accessed 19 February 2014].
[10] The genetically modified maize 1507 (Bt maize) was developed to confer resistance to specific harmful moth larvae for maize such as the European corn borer. It is currently authorised in the EU for food and feed uses, but authorisation for cultivation is on-going.

Committee. This action was closed by the Court following the Commission's submission of the proposal to the Regulatory Committee in February 2009, for a draft authorisation decision. The Committee, however, failed to deliver an opinion. In 2010, Pioneer launched a second action against the Commission for not having referred a proposal for an authorisation decision to the Council following the absence of opinion by the Regulatory Committee, in line with the comitology procedure applicable at the time.[11]

The Commission, in line with this ruling, referred the cultivation request to the Council where it was the responsibility of the Ministers to take a position by qualified majority on the request. The EFSA had already submitted a positive opinion on the request in 2005, 2006, 2008, 2011 and 2012.[12] On 11 February 2014 following a roundtable discussion (after countries backed a French-led push for formal talks rather than a 'written procedure'[13]) there was a split-vote among the Member States. The Commission is now obliged to approve the cultivation of maize 1507 (the first significant biotech crop in over a decade becoming the second GM maize crop in the EU) since the 19 countries opposed to cultivation did not have the required qualified majority to block the proposal.[14]

The DuPont Pioneer Communications Manager in Europe said after the Council vote,

> We are now confident that the European Commission, based on the seven positive safety opinions published by the EFSA, will adopt the decision for approval again as required under E.U. law. 1507 maize meets all EU regulatory requirements and should be approved for cultivation without further delay...The European Union has a legal obligation to itself, to its farmers and scientists and to its trade partners to follow the revised EU biotech legislation...[15]

Spain, the only country likely to widely cultivate maize 1507, has welcomed the authorisation and has urged the EU to 'allow farmers the technology that can solve real problems and reduce use of insecticides'.[16]

However, the legislative process surrounding the authorisation of maize 1507 has been criticised by environmental NGOs and Marco Contiero (Greenpeace's EU agriculture policy director) said:

> The Commission cannot ignore the scientific, political and legal concerns voiced by a large majority of countries, by two thirds of the European Parliament and supported by most EU citizens.[17]

MEPs (Members of the European Parliament) did not support the move saying it could endanger butterflies and moths urging the Commission to halt approval or renewal of GM crops until risk assessment methods are improved.[18]

On 12 February 2014 the European Parliament's Greens group threatened to table a motion of censure against the Commission, following its approval to authorise maize 1507.

The complications surrounding the authorisation of maize 1507 with the split stance of the Member States has led to a call for the revival of the stalled proposals tabled by the Commission three years previously (2010)[19]. The Commissioner for Health

[11] Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (**OJ L 184, 17.7.1999, p. 23**)

[12] Europa, **GMO: Commission asks Council to agree on its proposal to grant Member States more subsidiarity on cultivation** 6 November 2013 [accessed 17 February 2014]

[13] AGRAFACTS No. 02/14 10 January 2014

[14] AGRAFACTS No. 11/14 12 February 2014

[15] Truth about trade and technology, **DuPont Pioneer Seed Corn Clears EU Regulatory Hurdles, But...**20 February 2014 [accessed 17 March 2014]

[16] AGRAFACTS No. 11/14 12 February 2014

[17] *ibid*

[18] *ibid* and AGRAFACTS No. 04/14 17 January 2014

[19] European Commission **Proposal for a regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory** 13 July 2010, COM(2010) 375 final [accessed 19 February 2014]

and Consumer Policy, Tonio Borg, has welcomed resurrection of the plans 'to provide a solution to the current deadlock on the authorisation process...' [20]

Proposed changes in legislation

The Proposal for a Regulation revising Directive 2001/18/EC

In July 2010 the Commission published a draft proposal for a **Regulation revising Directive 2001/18** (COM(2010)375). [21] This revision would attempt to provide a legal basis for Member States to decide on GMO cultivation on grounds other than those based on scientific assessment of environmental and health risks. These include ethical and moral criteria, granting Member States more flexibility. Member States would be able to restrict or prohibit GMO cultivation in part or all of their territory without having to use the safeguard measures which up to now have not been backed by EFSA (though health and environmental concerns can continue to be raised under the existing safeguard clause). Decisions would not need to be authorised by the Commission, but Member States would have to inform other Member States and the Commission one month prior to the adoption of their measures (in the original proposal). The Member States would also have to respect the general principles of the Treaties and the Single Market, and be consistent with the international obligations of the EU.

The proposals are subject to the Co-decision procedure where both the Council and European Parliament have to reach an agreement on them.

The current status of the proposed Regulation

The initial proposals were met with opposition with France and Germany concerned that it could result in the fragmentation of the EU's internal market and cause problems with the World Trade Organisation. The European Economic and Social Committee stated that the draft proposal:

> ...creates more vagueness than certainty and could in practice result in a proliferation of (legally unstable) measures being adopted by the States and regions, which could affect the operation of the EU's internal market, the legal security of operators and the credibility of the system as a whole. [22]

The Council

In March 2011 EU environment Ministers met in Brussels to discuss a list of possible reasons why individual Member States could opt to ban GMO cultivation. **'Public morals'** including religious, philosophical and ethical concerns, **'social policy objectives'** including the preservation of certain farming types to maintain jobs, and **'cultural policy'** were amongst the options listed by the Commission. [23]

In March 2012 in a debate on the proposed revisions at the Environment Council no agreement could be reached due to blocking of the proposal by a minority of Member States. This minority included the UK, France and Denmark who cited various legal concerns.[24]

Due to the issues raised by the authorisation of maize 1507 the current Greek Presidency of the Council began exploring support for a revival of the discussions on the proposals. On 11 February 2014 a number of countries including the UK, Denmark and

[20] Europa, **GMO: Commission asks Council to agree on its proposal to grant Member States more subsidiarity on cultivation** 6 November 2013 [accessed 17 February 2014]

[21] European Commission **Proposal for a regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory** 13 July 2010, COM(2010) 375 final [accessed 19 February 2014]

[22] European Economic and Social Committee OPINION **on the Proposal for a Regulation 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 final [accessed 19 February 2014]

[23] Euobserver **EU states to discuss 'reasons' for national GMO bans** 10 March 2010 [accessed 18 February 2014]

[24] AGRAFACTS No. 11/14 12 February 2014

Luxembourg backed the re-opening of talks on the proposed revision, the first time since negotiations broke down in March 2012. In a Council meeting of Environment Ministers on the proposals on 3 March 2014 the UK broke from the previous blocking minority and a number of Member States expressed support for the compromise text. This led to a vote and formal adoption of the compromise text at the Environment Council on 12 June 2014.

The compromise text agreed by the Council included a number of proposed amendments to the Commission's original proposal.[25].Under the compromise text Member States would be able to request that the Commission notify bio-tech companies either during the authorisation process or once authorisation had been granted of a Member State's demand for the geographical scope of the authorisation be amended. That is that rather than an authorisation applying to the whole of the EU it would exclude certain Member State's territories as requested or agreed.

If the bio-tech company refuses to amend its authorisation the Member State would be able to notify the Commission of its intention to ban the cultivation of that GMO on the whole or part of its territory on a number of grounds outside those currently part of the EFSA assessment process. These include socio-economic reasons, agricultural policy reasons, town or country planning reasons, land-use reasons or on environmental grounds not already considered as part of the EFSA process. .

Member States would need to provide the Commission with a draft of the measures 75 days prior to their adoption for consideration. The Commission would consider whether or not the Member State's proposal made proper use of the powers provided within the Directive At the end of the 75 day 'standstill period', Member States could decide to amend the measures taking into account any comments made by the Commission or adopt them as originally proposed.[26]

In addition, Member States may revoke any measures in place on their territory and request that the authorisation be amended to include any previously excluded territories.

The European Parliament

The European Parliament adopted a negotiation position on the Commission's original proposals in July 2011. It wanted to amend the Commission's proposals in a number of ways. This included requiring Member States to take appropriate measures to avoid the unintended presence of GMOs in other products on their territory and in border areas of neighbouring Member States. Amendments were also included that would allow bans to be introduced on the basis of local environment concerns. Additionally, the European Parliament wanted a guarantee that restrictions or bans on cultivation of GMOs by Member States should not prevent biotechnology research from being carried out provided that all necessary safety measures are observed.

Given the recent European Parliament elections and the length of time that has passed since the Parliament adopted its negotiation position it may decide to re-visit its initial response. Whether the Parliament intends to do so will become clear of the next few months as formal business sessions in the Parliament get under way following the elections.

Timeline for negotiations

The Council has indicated that it expects to enter into trilogue negotiations with the European Parliament on the text of the final proposal in autumn 2014. This timetable will be dependent upon whether the European Parliament decides to re-visit its original negotiation position. The Parliament will hold its first plenary session following

[25] Council of the European Union, ***Proposal for Regulation amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs in their territory: Revised Compromise proposal in view of Council Political Agreement (first reading),*** 23 May 2014 [accessed 1 July 2014]

[26] AGRAFACTS No. 15/14 26 February 2014

the May elections between 1-3 of July and will begin fully considering formal business in September.

Responses

Opposition remains towards the proposed changes from both biotech companies and environmental NGOs. [27]Biotech firms argue that the opt-outs could undermine ESFA's credibility, the integrity of the internal market and science based decision making. [28] Greenpeace raise concerns that Member States that want to ban GM crops will be exposed to legal challenges and forced to 'do deals' with biotech lobbyists. [29]

In addition, in recent weeks comments have been made about the potential impacts on the proposal of the on-going EU-US trade negotiations known as the Transatlantic Trade and Investment Partnership (TIPP). Agriculture is one of the more contentious issuesin the negotiations. The US Agriculture Secretary has called for a harmonisation of US and EU authorisation process for GMOs expressing concern at the length of time GMO authorisations take within the EU.[30] Environment NGO's such as Greenpeace[31] and Friends of the Earth Europe[32] have expressed concerns about the implications and influence of the TIPP on the EU's GMO approvals process.

[27] AGRAFACTS No. 17/14 5 March 2014
[28] AGRAFACTS No. 17/14 5 March 2014
[29] AGRAFACTS No. 17/14 5 March 2014
[30] Euractiv, ***US wants Science to settle GMO debate in trade deal with EU,*** 18 June 2014 [accessed 26 June 2014]
[31] *Ibid*
[32] Friends of the Earth Europe, ***EU-US Trade deal A bumper crop for big food?,*** October 2013 [accessed 26 June 2014]:

Further information

For further information on the/about **Genetically Modified Organisms (GMOs): The authorisation process for cultivation**, please contact **Nia Seaton** (**Nia.Seaton@Wales.gov.uk**), Research Service.

See also:

- European Commission **Questions and Answers on EU's policies on cultivation and imports of GMOs** 6 November 2013

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