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

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Introduction

Whilst the Welsh Government has devolved competence over policy for genetically modified organisms (GMOs) in Wales, decisions over cultivation of GMOs is subject to an authorisation process carried out by the EU. This authorisation process involves several stages including scientific risk assessment, public consultation and a decision by Member States on whether or not to approve or reject a proposal by the European Commission ('the Commission') for a GMO to be cultivated in the EU.

The Welsh Government does not have a direct voice in this process as it is the UK Government, as the Member State, that takes decisions on behalf of the UK as a whole. Therefore, if the Welsh Government has concerns about GMOs being considered for authorisation it must raise these via the UK Government.

This process of authorisation has proven problematic as in many cases Member States have failed to reach a qualified majority concerning GMO products, with a clear split emerging within the Council between the pro- and anti-GMO voice. This has led to long delays in the decision-making process. Where the Member States fail to reach a qualified majority, the current rules allow the Commission to take a decision to grant EU level authorisation provided that a positive opinion is reached after the completion of a risk assessment. However the Commission has been reluctant to authorise applications following a lack of support from Member States.

Some Member States have criticised the current authorisation process for failing to sufficiently respect subsidiarity and the rights of Member States to ban GMOs in their territory.

In 2010 the Commission set out a proposal for a Regulation aimed at addressing some of these concerns. The 2010 proposals aimed to give Member States greater flexibility to restrict or prohibit GMO cultivation on all or part of their territory based on ethical and moral criteria outside the current scientific assessment process. In December 2014 an agreement was reached between the European Council and European Parliament on the final details of this new Regulation. The proposals had stalled in negotiations in Council for almost four years, until the Greek EU Presidency brokered a compromise deal between Member States in June 2014.

The wider issue of subsidiarity in the GMO process has been identified as a priority in the 2015 European Commission Work Programme, published on 16 December. The Work Programme makes a commitment to review the entire GMO authorisation process in 2015.

This Research Note provides a summary of the current GMO authorisation process detailing the changes approved by agreement on the 2010 proposals. This Note will be updated when the Commission launches the planned review of the overall GMO authorisation process this year.

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 food

[1] Regulation (EC) N° 1829/2003 [accessed 14 February 2014]

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.

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.

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 to be a danger to the **environment and/or human health** within their territory. This also applies to Regulation 1829/2003. 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

[2] Directive **2001/18/EC** [accessed 14 February 2014]
[3] **EFSA** [accessed 14 February 2014]
[4] **EFSA Journal** [accessed 14 February 2014]
[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**)

Council) for a decision. If the Council fails to respond to the proposals within a set timeframe the Commission will adopt the proposal.[9]

Safeguard measures to date have rarely been backed by the EFSA. France, Germany, Austria, Bulgaria, Greece, Hungary, Luxembourg, Poland and Italy have attempted to ban maize MON810 on their territories, with many of the Member States' evidence for the ban already deemed invalid by EFSA.

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 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 on the request by qualified majority. 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

[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.

[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

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 led to a call for the revival of the stalled proposals tabled by the Commission three years previously (2010) [19].

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).[20] This revision aimed 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 such as ethical and moral criteria, granting Member States more flexibility. The Commission proposes to include a new article (26b), which would be applicable to all GMOs that will be authorised for cultivation in the EU, either under Directive 2001/18 or under Regulation 1829/2003.

It was proposed that 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 (although health and environmental concerns could 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 were subject to the Co-decision procedure where both the Council and European Parliament had to reach an agreement on them. An agreement on the proposals was reached in December 2014 following years of negotiations and stalled discussions.

The Council

The proposed regulation was initially opposed by several Member States during discussions in March 2012, where various legal concerns were raised. [21] This led to a break down in the discussions which were not re-opened again until March 2014 following issues raised by the authorisation of maize 1507. In a Council meeting of Environment Ministers 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 included a number of proposed amendments to the original proposal.[22] These included Member States being able to request that the Commission notify bio-tech companies

[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]
[20] 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]
[21] AGRAFACTS No. 11/14 12 February 2014
[22] 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]

either during the authorisation process or once authorisation had been granted of a Member State's demand for the geographical scope of the authorisation to be amended. In other words rather than an authorisation applying to the whole of the EU it would exclude certain Member States' territories as requested or agreed.

Under the compromise text if the bio-tech company refused 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 included 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.

In addition under the compromise text, Member States could have revoked 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, a move opposed by many in the Council.[23] 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.

[23] AGRAFACTS No. 87-14 26 November 2014

In the second round of trilogue talks on 25 November 2014, the European Parliament disagreed with the Council by wanting to make it voluntary rather than obligatory that countries intending to ban GMOs must first discuss an opt-out with biotech firms to limit the scope of their sales applications. The Council claimed that such discussions would ensure that countries that do not allow cultivation would be less open to legal challenges and would reduce the need to resort to adopting bans and justifying them. However MEPs were concerned that the change could increase the influence of biotech companies such as Syngenta or Monsanto.[24]

Outcome of negotiations

On 3-4 December 2014 negotiations came to an end when a compromise was reached between the Council and the European Parliament. The informal deal was approved by the Council's Permanent Representatives Committee (COREPER) on 10 December 2014.

It was agreed that countries will be able to ban GM crops based on an approved list of grounds that includes town and country planning, land use, socio-economic impacts, co-existence and public policy.[25] The environmental policy objectives used for justification of a ban relate to environmental impacts other than the risks to health and environment assessed during the scientific risk assessment carried out by the EFSA. The new deal did not include MEPs' demands for a wider list of grounds including specific environmental reasons. It was agreed that countries would have the choice of whether they negotiate opt-outs with biotech firms first or proceed immediately with bans. The agreement also requires that Member States should ensure that GMO crops do not contaminate other products, and attention should be paid to preventing cross-border contamination with neighbouring countries where GMOs are banned.

The final deal was voted through by the Council and

[24] AGRAFACTS No. 87-14 26 November 2014

[25] Council of the European Union, ***EU countries get more latitude on the cultivation of GMOs***, 10 December 2014 [accessed 17 December 2014]

the European Parliament in a plenary vote on 13 January 2015. The agreement reached on the Regulation is expected to come into effect in the spring of 2015 and the approved Regulation will amend Directive 2001/18.

Responses

S&D[26] spokesperson on health and climate, MEP Matthias Groote, said:

> This report includes most of S&D's priorities, such as the choice of the environmental legal basis, a more extensive list of reasons for banning, the need to have binding measures on coexistence in order to avoid the contamination of traditional cultivations by GMO cultivations, reinforcement of the risk evaluation method by the European Food Safety Evaluation (EFSA) and far greater transparency in the banning procedure.[27]

According to Greenpeace, the agreed text is legally weak.[28] Commenting on the outcome of the vote, Marco Contiero, Greenpeace EU agriculture policy director said:

> Environment ministers say they want to give countries the right to ban GM crop cultivation on their territory, but the text they have agreed does not give governments a legally solid right. It ties their hands by not allowing to use evidence of environmental harm to ban GM cultivation. This leaves those countries that want to say 'no' to GM crops exposed to legal attacks by the biotech industry.[29]

Biotech firms argue that the opt-outs could undermine ESFA's credibility, the integrity of the internal market and science based decision making.[30]

The plans aim to speed up the approval of new GM crops at EU-level allowing pro-GMO countries such as Spain and Portugal the option of growing new varieties. However according to Agra Facts[31] many commentators remain sceptical over whether the deal will change the rate of approvals.

Further information

For further information on the/about **Genetically Modified Organisms (GMOs): The authorisation process for cultivation**, please contact **Nia Seaton** (**Nia.Seaton@Assembly.Wales**), 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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Enquiry no: 14/3318

[26] Group of the Progressive Alliance of Socialists and Democrats in the European Parliament
[27] Farming UK *EU countries granted flexibility to ban GMO crops*, 12 November 2014 [accessed 18 November 2014]
[28] Greenpeace EU Unit, *Member states agree on right to ban GMO cultivation at national level*, 12 June 2014 [accessed 18 December 2014]
[29] Greenpeace EU Unit, *New EU law grants countries right to ban GM crops but leaves them exposed to industry attacks*, 4 December 2014 [accessed 18 December 2014]
[31] Agra Facts No.90-14