

# Genetically modified food and feed: the authorisation process

EU Policy Update

August 2015

## Introduction

On 22 April 2015, the European Commission tabled proposals<sup>1</sup> to reform the authorisation process for genetically modified (GM) food and feed, amending **Regulation 1829/2003**<sup>2</sup>. President of the European Commission, Jean-Claude Juncker, identified this as one of the priority dossiers for his mandate.

The draft proposals give flexibility to allow individual Member States to restrict or prohibit the use of GM feed and food (such as soy bean and maize) in their own territory. This would be based on grounds other than health and the environment, elements that are assessed by the European Food Safety Agency (EFSA).

This EU Policy Update gives: the background context to the proposals; a summary of the new proposals; the relevance to Wales; the UK Government's position; and the progress of the dossier in the EU.

## Background context to the proposal

### The current authorisation process

**Regulation (EC) No 1829/2003** is the current legislative framework for the authorisation of GM food and feed.<sup>3</sup> The Regulation establishes a centralised procedure whereby products are approved at **EU-level**.

<sup>1</sup> **COM(2015)177, 2015/0093 (COD)** 22 April 2015 [accessed 24 April 2015]

<sup>2</sup> Regulation (EC) **N° 1829/2003** [accessed 24 April 2015]

<sup>3</sup> *Ibid*

### Application

The use of GM products for food and feed are authorised at EU-level following an **application by a biotech company**. Applications must be submitted to a national authority under Regulation 1829/2003 and must comply with the requirements set out in **Commission Implementing Regulation (EU) 503/2013**.<sup>4</sup> Applications must include:

- purpose and scope;
- all relevant data, studies and analysis of the results;
- monitoring plan;
- labelling proposal;
- detection method; and
- an indication of confidential information.

The national authority must acknowledge receipt of the application within 14 days. It then sends the application to the **European Food Safety Agency (EFSA)**, the independent European agency which provides scientific risk assessment regarding EU food and feed safety to the European Commission and Member States. EFSA makes the application summary available to the public.

### Risk assessment

EFSA assesses the risks of the GMO (genetically modified organism) to the **environment, human health and animal safety** in the EU on scientific grounds.

**EFSA's GMO Panel** carries out the risk assessment.<sup>5</sup> It may give recommendations on labelling or conditions of the use and sale of the product. Normally, EFSA performs the risk assessment within six months of receiving the application and issues a scientific opinion published in the EFSA Journal.<sup>6</sup>

<sup>4</sup> EFSA Journal, **New Commission Implementing Regulation on Risk Assessment of GM plant applications: novel elements and challenges**, 2013, 11(12) [accessed 28 April 2015].

<sup>5</sup> EFSA, **GMO** [accessed 27 April 2015]

<sup>6</sup> **EFSA Journal** [accessed 24 April 2015]



EFSA submits its opinion to the Commission and to the Member States for consideration.

### Public Consultation

ESFA's opinion is made available to the public. Once published the public may comment (for 30 days) on the Commission website<sup>7</sup> for applications under Regulation 1829/2003.

### Final Decision

Within 3 months of receiving EFSA's opinion the Commission should issue a proposal to grant or refuse the authorisation. If the Commission proposal differs from EFSA's opinion, it must be explained why.

Representatives of Member States approve the Commission's proposal by qualified majority in the **Standing Committee on Plants, Animals, Food and Feed**.

If the Committee does not approve or reject the proposal by a qualified majority, the Commission may summon an **Appeal Committee**.

If the Appeal Committee fails to reach an opinion by a qualified majority, **the Commission can adopt its original proposal**.

Authorisations are valid for a maximum of **10 years and are renewable**.

Regulation 1829/2003 already contains provisions (Article 34) allowing the Commission or Member States to adopt emergency measures against the placing on the market/use of an authorised GMO, where it appears that the product is likely to have a serious risk to health or the environment.

Since the entry into force of Regulation 1829/2003, **Member States have never expressed a qualified majority** in favour or against a Commission decision due to their divided opinions on GMOs. As a result, the authorisation decisions have been adopted by

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<sup>7</sup> European Commission **Public consultations on GM food & feed authorisation applications under Regulation 1829/2003** [accessed 19 February 2014]

the Commission without the support of the Member States' committee opinion.

### Other 'legitimate factors'

Regulation 1829/2003 provides that other 'legitimate factors' may be taken into account by the European Commission where appropriate in addition to the EFSA's scientific assessment. A definition of what these might be is not provided and the Commission has not used these provisions due to uncertainties over the legality of their use in different circumstances. In addition under the current Regulation, it could only do this for the EU as a whole.

### The extent of the authorisation of GM feed and food in the EU

To date, there are **58 GM food and feed products authorised in the EU**, mostly for animal feed. The EU imports over 33 million tonnes of GM soya beans, worth more than £8.6 billion each year.<sup>8</sup> The European Feed Manufacturers' Association estimates that **the EU feed industry annually imports more than 70% of its maize, soya and rapeseed requirements**. Brazil, Argentina, Paraguay and the USA are major producers of soya beans and soya bean meal, almost all of which is now GM.<sup>9</sup>

Although considered to be a high proportion, it is not possible to quantify the proportion of GM derived products within imported animal feed as there is no requirement for importers to declare the quantities. These imports are considered to be unavoidable by the EU feed industry because the EU is not self-sufficient in protein-rich feed.<sup>10</sup>

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<sup>8</sup> Farmers Guardian, **EU Commission warned plans to nationalise GM approvals could 'damage livestock industry'**, 23 April 2015 [accessed 28 April 2015]

<sup>9</sup> Food Standards Agency, **GM material in animal feed**, 2 July 2013 [accessed 27 April 2015]

<sup>10</sup> Food Standards Agency, **GM material in animal feed**, 2 July 2013 [accessed 27 April 2015]



## Summary of the main points of the proposal

The Commission's stance is that the current legal framework for decision making on GM food and feed needs to be amended as it does not allow for individual concerns of Member States to be taken into account.

### National bans

The Commission's proposal<sup>11</sup> introduces new provisions allowing **Member States to restrict or prohibit the use of GM feed or food in part or all of their territory despite being approved at EU-level**. This will amend Regulation 1829/2003. These additional powers granted to Member States to adopt national bans on GM food and feed would only apply after these products have been authorised.

This proposal mirrors the recent reform of the GMO authorisation for cultivation process, **Directive (EU) 2015/412**, revising Directive 2001/18 (for more information see the Research Service Research Note<sup>12</sup>). This has given Member States stronger legal rights to ban the cultivation of GMOs on their territories.

The proposed measures on GM food and feed would need to be compatible with the internal market and with the institutional framework of the EU. Therefore the restrictions or prohibitions adopted under the proposed Regulation refer to the *use* and not the free circulation and imports of GM food and feed.

### Grounds for a ban

Under the draft proposals, each Member State wishing to ban the use of GM food and feed would have to justify the move on a case-by-case basis **'taking into account the GMO in question, the type of measure envisaged and the specific**

**circumstances at national or regional level that can justify such an opt out'**. Any measures adopted by Member States have to be **'reasoned and based on compelling grounds'** and they have to respect the principles of 'proportionality and non-discrimination' (Article 1).

To avoid interference with competences already granted under the Regulation 1829/2003, relating to risk assessment, the proposals state that **Member States will not be able to use grounds which are related to health and environmental risks considered by EFSA**. These should continue to be dealt with in accordance with the EFSA procedure under Regulation 1829/2003.

### Standstill period

The Member State wishing to impose a ban or restriction would need to submit a draft of the measures and corresponding justification to the Commission. The Commission shall immediately notify the other Member States. The proposals include a 3 month 'standstill period' whereby the Commission and other Member States can make comments on a Member State's intentions to ban the use of a GM food and feed product.

On the expiry of the established standstill period, the Member State would be able to adopt the measures as originally proposed or amended to take into account the Commission's or Member States' comments. There is no duty for the Member State wishing to impose a ban to take the comments into account.

### Grace period

The proposals state that any bans or restrictions under the proposed Regulation should provide for a 'reasonable period of time' during which existing stocks of the GM food or feed (which could previously be used legally) could be used up before the ban is adopted.

<sup>11</sup> **COM(2015)177, 2015/0093 (COD)** 22 April 2015 [accessed 24 April 2015]

<sup>12</sup> Research Service Research Note, **Genetically Modified Organisms (GMOs): The authorisation process for cultivation**, January 2015 [accessed 24 April 2015]

## Relevance to Wales

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 in the European Council in terms of approving an application by a company for the use of GM food and feed at EU-level.

Regulation 1829/2003 is implemented in Wales through the following Regulations:

- **The Genetically Modified Feed (Wales) Regulations 2004;**
- **The Genetically Modified Food (Wales) Regulations 2004;**
- **The Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005.**

GM food and feed are currently used in Wales. The new proposal would allow the Welsh Government to opt to restrict or prohibit GM food and feed products in Wales.

The Welsh Government is yet to release a statement in response to the Commission's GM food and feed proposals. However, the Deputy Minister for farming and food, Rebecca Evans, has made a statement in relation to the recent reform of the GMO authorisation for cultivation process, Directive (EU) 2015/412.<sup>13</sup> She stated that:

This development will help us in our delivery of our GM policy which is to maintain a restrictive and precautionary approach to GM crop cultivation.<sup>14</sup>

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<sup>13</sup> Welsh Government, **Written Statement - The nationalisation of genetically modified crop cultivation decisions in the European Union**, 11 February 2015 [accessed 29 April 2015]

<sup>14</sup> *Ibid*

Theoretically, a case could arise whereby Wales might ban the use of a GM food or feed product whilst the UK Government may allow its use in England. Therefore issues could arise relating to cross-border contamination.

The National Assembly's Environment and Sustainability Committee has been following the Commission's proposals and has written to the Deputy Minister for Health, Vaughan Gething, to determine the Welsh Government's position and the potential impacts of the proposals on Wales. The letter will be considered by the Committee in the autumn term of 2015.

## UK Government position

*Detail will be added to this section when more information is available.*

## Stakeholder responses

**The EU Food and Feed Chain partners**, which includes EU farming body Copa-Cogeca and bodies representing EU feed and food manufacturers, millers and the biotech industry, have asked for the Commission to reconsider its draft plans to renationalise the GM authorisation process. The coalition states that the proposals would 'reverse the economic achievements of the European Customs Union and the single market'. The coalition argues that 'properly implementing the existing legislation should be the main priority for the Commission before starting further reflections on changing the current market authorisation procedure.'<sup>15</sup>

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<sup>15</sup> EU Food and feed chain partners, Press Release, **EU food and feed chain partners reject EU Commission move to undermine the Internal Market for Agri-food products**, 8 April 2015 [accessed 27 April 2016]



The coalition said the policy **does not logically follow on from the situation with GMO cultivations** as while very few GM crops are currently grown in the EU, there is already a large annual trade in GM imports.<sup>16</sup>

**Friends of the Earth campaigner, Mute Schimpf**, has accused the President of the European Commission, Jean-Claude Juncker, of breaking a commitment to make the decision-making process more democratic stating that 'his new draft law is a smokescreen which fails to deal with the democratic deficit at the centre of the debate on GM foods'.<sup>17</sup>

**NFU's chief science and regulatory affairs adviser, Dr. Helen Ferrier**, said:

Pig and poultry sectors are especially vulnerable, where feed is 55-65% of cost of production. Any increase in price of feed would put significant strain on food producers and would risk making the EU uncompetitive.<sup>18</sup>

## Progress of dossier in European institutions

*This section will be updated as the negotiations take place in Brussels and the official positions of the EU Institutions become clear.*

The proposals are subject to the ordinary legislative procedure where both the Council and European Parliament has to reach an agreement on them.

### The Council

Member State representatives of the Agriculture and Fisheries Council expressed strong concerns regarding the workability of the proposals during a

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<sup>16</sup> Farmers Guardian, **EU food chain coalition urges Commission to drop plans to nationalise GM approvals**, 17 April 2015 [accessed 27 April 2015]

<sup>17</sup> Friends of the Earth, **Juncker's empty GMO offer – is TTIP already in force?** 22 April 2015 [accessed 27 April 2015]

<sup>18</sup> NFU, **NFU rejects re-nationalising decisions on GM feed**, 23 April 2015 [accessed 27 April 2015]

debate on 13 July 2015.<sup>19</sup> There was concern that the proposals lacked legal clarity and would not allow Member States to adopt restrictive or prohibitive measures on a strong legal basis. There was suggestion that the proposal could raise problems of compatibility with the internal market and World Trade Organisation rules. Austria, Denmark and Belgium argued that a common approach at EU as regards GM should be maintained.

The majority of Member States criticised the absence of impact assessment accompanying the proposal; they called on the Commission to carry out an impact assessment to enable them to examine the proposal reasonably.

### European Parliament

MEPs of the Environment Committee recommended rejection of the proposals during a debate held on 16 July 2016. The chair of the Committee and Rapporteur on the dossier, Giovanni La Via, drafted a report calling for the outright rejection of the proposals. The Rapporteur highlighted that all political groups are very sceptical over the proposals. Shadow Rapporteurs supported the Draft Report on the grounds that: the proposal would not provide sufficient legal certainty to Member States that wish to take measures to ban GM food and feed; would fragment the internal market; and would not be compatible with WTO rules.

MEP Eickhout (Greens/EFA, Netherlands) requested the inclusion of a section in the Draft Report that would ask the Commission to present a new proposal on the issue which was supported by a majority of MEPs.

However, European Commission representatives have said that there will be no 'plan B' and any rejection would lead to the continuation of the current situation.

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<sup>19</sup> Agriculture and Fisheries Council: **Outcome of the Council Meeting**, 3402nd Council meeting, Brussels, 13 July 2015

The deadline for tabling amendments to the EP Draft Report is set for 16 September 2015. Environment Committee MEPs are scheduled to vote on the Draft Report on 12/13 October 2015. A vote in Plenary is set for 24 November 2015.

## Further information

For further information on the/about **GENETICALLY MODIFIED FOOD AND FEED: THE PROCESS FOR AUTHORISATION**, please contact **KATY ORFORD** ([katy.orford@assembly.wales](mailto:katy.orford@assembly.wales)) or **NIA SEATON** ([nia.seaton@assembly.wales](mailto:nia.seaton@assembly.wales)) Research Service.

### See also:

- Research Service Research Note, **Genetically Modified Organisms (GMOs): The authorisation process for cultivation**
- Research Service **Blog Post** on the new proposal
- European Commission **GMO authorisations for food and feed**
- **Food Standards Agency website**

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