



## Half a century of undue delays in the EU Approval of GM Products

The EU's strict laws for GM products state that approval decisions have to be taken quickly once a product is declared safe by independent scientists. However, the European Commission routinely delays such decisions, often for years. The combined undue delay for all GM products? 51 years.

### Steps in the EU approval system for GMOs: How does it work? And *does* it work?

The EU has one of the world's strictest approval procedures for GM products. First, the European Food Safety Authority (EFSA) makes an extensive scientific risk assessment. If EFSA finds the product in question as safe as its non-GM counterpart, a political decision must then be made. This decision-making phase is administered by the European Commission and involves the Member States. EU legislation requires the European Commission to stick to specific timelines<sup>i</sup>:

- It has a maximum of 3 months to ask the Member State representatives to vote (2<sup>nd</sup> column from the right in below table).
- If they vote and do not reach a qualified majority, the Commission has to hold another vote within 2 months<sup>ii</sup> (right column).

However, the Commission has formally admitted that it regularly fails to comply with legal timelines when it comes to GM authorisations<sup>iii</sup>.

### Timelines for GM products with a positive EFSA safety opinion and awaiting Commission action:

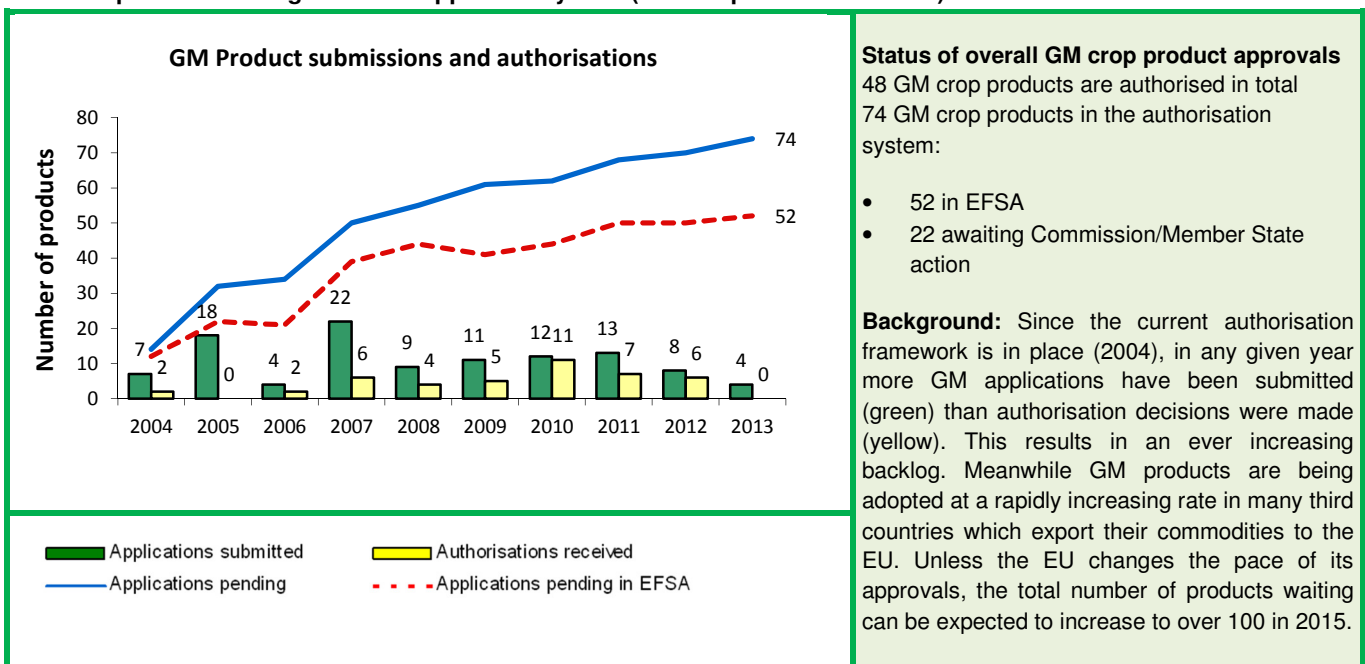
Product (scope)	Trait, company	Application Received by EFSA <sup>iv</sup>	Publication of EFSA Opinion	Months (m) and days (d) waiting for the European Commission (EC) to schedule first vote <sup>v</sup> : maximum: 3 months	Months (m) and days (d) waiting for the EC to schedule second vote <sup>vi</sup> : maximum: 2 months
<b>Applications for food/ feed/ imports</b>					
Rapeseed MS8xRF3 (ff) (renewal)	male sterility, HT <sup>vii</sup> , Bayer	06/2007	22/09/2009	Voted after 43 m 04 d (26/04/2013)	01m 08 d and counting
Rapeseed GT73 (ffip - renewal)	HT, Monsanto	06/2007	15/12/2009	41 m 09 d and counting	
Maize MON863 (ffip - renewal)	IR <sup>viii</sup> , Monsanto	06/2007	30/03/2010	38 m 04 d and counting	
Maize MON89034x1507x MON88017x59122 (ffip)	IR, HT, Monsanto, Dow AgroSciences	10/2008	27/09/2010	32 m 07 d and counting	
Maize MON89034x1507xNK603 (ffip)	IR, HT, Monsanto, Dow AgroSciences	02/2009	27/09/2010	32 m 07 d and counting	
Cotton MON531 (ffip - renewal)	IR, Monsanto	06/2007	16/09/2011	20 m 18 d and counting	
Cotton MON1445 (ffip - renewal)	HT, Monsanto	06/2007	16/12/2011	17 m 18 d and counting	
Cotton MON531xMON1445 (ff - renewal)	IR, HT, Monsanto	06/2007	28/03/2012	14 m 06 d and counting	
Rapeseed MS8, RF3 & MS8xRF3 (ffip - extension of scope)	male sterility, HT, Bayer	06/2010	26/09/2012	Voted after 07 m 00 d (26/04/2013)	01m 08 d and counting
Soybean MON87705 (ff)	altered for healthier oil, HT, Monsanto	02/2010	30/10/2012	07 m 04 d and counting	
Maize MON87460 (ffip)	drought tolerant, Monsanto	05/2009	15/11/2012	06 m 19 d and counting	
Maize MON810 (extension of scope - pollen)	IR, Monsanto	03/2012	18/12/2012	05 m 16 d and counting	
Oilseed Rape GT73 (ffip) (extension of scope)	HT, Monsanto	08/2010	12/02/2013	03 m 22 d and counting	
<b>Applications including cultivation in their scope</b>					
Maize 1507 (c)	IR, Pioneer, Dow AgroSciences	11/2000	03/03/2005	voted after 47 m 22 d (25/02/09)	51 m 09 d and counting
Maize Bt11(ipc)	IR, Syngenta	05/1996	19/05/2005	voted after 45 m 06 d (25/02/09)	51 m 09 d and counting
Maize NK603 (ffipc)	HT, Monsanto	08/2005	11/06/2009	47 m 23 d and counting	
Maize MON810 (ffipc - renewal)	IR, Monsanto	06/2007	30/07/2009	46 m 04 d and counting	
Maize MON88017 (c)	IR, HT, Monsanto	04/2008	10/11/2011	18 m 24 d and counting	
Maize GA21 (ffipc)	HT, Syngenta	07/2008	16/12/2011	17 m 18 d and counting	
Soybean MON 40-3-2 (c)	HT, Monsanto	11/2005	21/06/2012	11 m 13 d and counting	
Maize 59122 (ffc)	IR, Pioneer/ Dow AgroSciences	10/2005	13/03/2013	02 m 21 d and counting	
<b>Accumulated undue delay per column</b>				506 m 22 d	105 m 04 d
<b>ACCUMULATED UNDUE DELAY<sup>ix</sup></b>				<b>611 m 26 d = 51 years</b>	

## Why does this matter?

The EU is the world's biggest importer of agricultural commodities. Many of these imports are based on genetically modified (GM) crops. They are grown almost exclusively in countries outside Europe; where farmers have the choice between conventional and GM varieties. Today, GM varieties are the standard for soybeans, mainly imported to feed our farm animals, and cotton, for our textiles. We also import GM maize and rapeseed (colza) to meet our needs. The EU has become a net importer and has outsourced arable land nearly the size of Germany's entire territory to other parts of the world. Despite its import dependency, the EU is putting up "regulatory barriers", which have already resulted in trade disruptions and higher prices for key agricultural commodities.

If a given GM product is approved for cultivation in the Americas, but it is not (yet) approved for import into the EU, this can result in serious problems for international trade. Shipments with traces of products not yet approved in the EU could be turned away from European ports or diverted to Asia where demand is even higher. The backlog of EU authorisations for GM imports, combined with the fact that European farmers are not given the choice to grow most GM crop varieties, contributes to rising food prices, undermines the competitiveness of European farmers, increases the EU's import dependency, and creates legal uncertainty for import operators.

## The GM product backlog of the EU approvals system (status update 3 June 2013)



## Do you want to know more?

More detailed information about the inconsistency between legally prescribed timelines and the administrative practice has been published by the EU Commission and by EuropaBio<sup>x</sup>. Check for updates to this document at <http://www.europabio.org/filter/agricultural/type/position> or [contact](#) EuropaBio for more information. The detailed report 'Approvals of GMOs in the European Union' (2011) and the more concise report "Failures of the EU authorisation system for GMOs" (2013) are available on the EuropaBio website, as are [factsheets](#) on issues such as product safety and trade in agriculture.

<sup>i</sup> Timelines according to Reg (EC) 1829/2003, Art 7 and Council Decision 1999/468/EC Art 5.4.

<sup>ii</sup> 2 months maximum under the new procedure involving the Appeal Committee (for some products under the old procedure involving Council even "without delay").

<sup>iii</sup> Reply to MEP question E-004184/2012: <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-004184&language=EN>. The Commission sometimes prefers to postpone a decision by referring an application with a positive opinion back to EFSA, claiming that risk assessment requirements have evolved in the meanwhile and that therefore an applications whose risk assessment was concluded several years ago may need an additional EFSA safety opinion. Experience shows that EFSA usually confirms the substance of the earlier assessment. This document measures the delays from the publication of the initial EFSA opinion for each application. In exceptional circumstances, the applicant and the Commission may agree to find another solution (which may result in a delay).

<sup>iv</sup> Where the application date is before EFSA creation (2002), it refers to the date of application to Member State authorities.

<sup>v</sup> Standing Committee or Regulatory Committee

<sup>vi</sup> Appeal Committee or Council

<sup>vii</sup> HT: herbicide tolerant

<sup>viii</sup> IR: insect resistant

<sup>ix</sup> The undue delay for each application was calculated by deducting from the total delay of the respective pending application since the publication of the respective EFSA opinion the allowed delays for each vote (3 or 2 months). To obtain the accumulated undue delay, the undue delays for each pending application were added.

<sup>x</sup> Evaluation of the EU legislative framework including two studies commissioned by DG SANCO:

[http://ec.europa.eu/food/food/biotechnology/evaluation/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm); EuropaBio report (2011) "Approvals of GMOs in the European Union": [www.europabio.org/agricultural/positions/approvals-gmos-european-union](http://www.europabio.org/agricultural/positions/approvals-gmos-european-union)