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44 years of 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 delay for all GM products? 44 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[i]:

- It has a maximum of 3 months to ask the Member State representatives to vote.
- If they vote and do not reach a qualified majority, the Commission has to hold another vote within 2 months[ii].
- In exceptional circumstances, the applicant and the Commission may agree to find another solution (which may result in a delay)[iii].

The timelines foreseen in EU legislation are regularly exceeded. This document explains why this matters.

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

Timelines not compliant with EU law | Timelines compliant for the moment | Products for EU cultivation

Product	Application Received by EFSA[iv]	Publication of EFSA Opinion	Months (m) and days (d) waiting for the Commission to schedule first vote[v]: **maximum: 3 months**	Months (m) and days (d) waiting for the Commission to schedule second vote[vi] **maximum: 2 months**	Days after Council/ Appeal vote - waiting for approval
1507 maize (c)	11/2000	03/03/2005	voted after 47 m 22 d (25/02/09)	44 m 11 d and counting	
Bt11 maize (ipc)	05/1996	19/05/2005	voted after 45 m 06 d (25/02/09)	44 m 11 d and counting	
LL Rice62 (ffip)	08/2004	30/10/2007	60 m 06 d and counting		
NK603 maize (ffipc)	08/2005	11/06/2009	40 m 25 d and counting		
MON810 maize (ffipc) (renewal)	06/2007	30/06/2009	40 m 06 d and counting		
MS8xRF3 rapeseed(ff) (renewal)	06/2007	22/09/2009	37 m 14 d and counting		
GT73 oilseed rape(ffip) (renewal)	06/2007	15/12/2009	34 m 21 d and counting		
MON863 maize (ffip) (renewal)	06/2007	30/03/2010	31 m 06 d and counting		
MON89034x1507xMON88017x59122 maize (ffip)	10/2008	27/09/2010	25 m 09 d and counting		
MON89034x1507xNK603 maize (ffip)	02/2009	27/09/2010	25 m 09 d and counting		
MON531 cotton (ffip) (renewal)	06/2007	16/09/2011	13 m 20 d and counting		
MON88017 maize (c)	04/2008	10/11/2011	11 m 26 d and counting		
MON1445 cotton (ffip) (renewal)	06/2007	16/12/2011	10 m 20 d and counting		
GA21 maize (ffipc)	07/2008	16/12/2011	10 m 20 d and counting		
MON 531xMON1445 cotton (ff) (renewal)	06/2007	28/03/2012	7 m 8 d and counting		
MON 40-3-2 soybean (c)	11/2005	21/06/2012	4 m 15 d and counting		
Bayer MS8, RF3& MS8x RF3 oilseed rape (ffip) (extension of scope)	23/06/2010	26/09/2012	1 m 10 d and counting		
MON87705 soybean (ff)	25/02/2010	30/10/2012	0 m 5 d and counting		
Accumulated undue delay per column			446 m 20 d	88 m 22 d	
ACCUMULATED UNDUE DELAY[vii]			**534 months 42 days = 44.6 years**		

EuropaBio
The European Association for Bioindustries

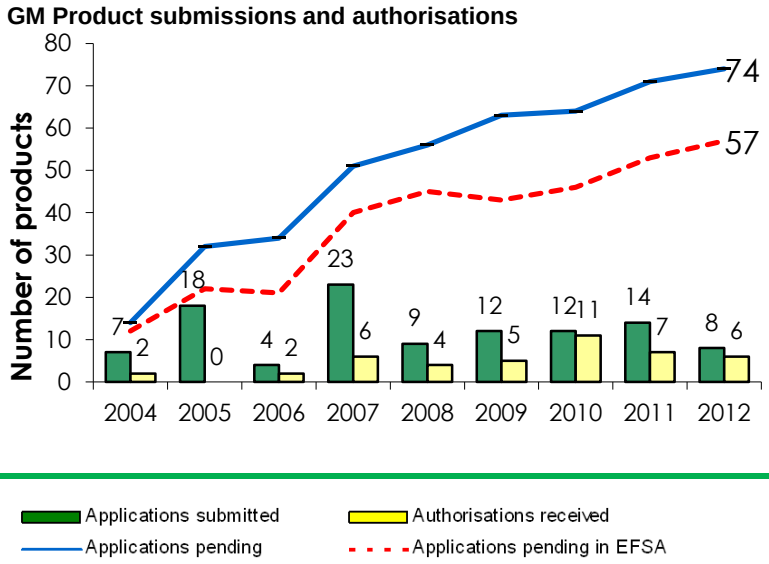
Why does this matter?

The EU is not currently able to produce all it needs. It imports grain commodities worth billions of euros every year, especially soy and maize to feed European farm animals[viii]. The EU has outsourced arable land nearly the size of Germany's entire territory to other parts of the world to produce our animals' food. Most of the imported animal feed is from the Americas and is genetically modified.

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 of overall GM crop product approvals
48 GM crop products are authorised in total
74 GM crop products in the authorisation system:

- in EFSA
- 18 awaiting Commission/Member State action

Background: Since the current authorisation framework is in place (2004), in any given year more GM applications have been submitted (green) than authorisation decisions were made (yellow). This results in an ever increasing backlog. Meanwhile GM products are being adopted at a rapidly increasing rate in many third countries which export their commodities to the EU. Unless the EU changes the pace of its approvals, the total number of products waiting can be expected to increase to over 100 in 2015.

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[ix]. Check for updates to this document at http://www.europabio.org/filter/agricultural/type/position or contact EuropaBio for more information. The full report 'Approvals of GMOs in the European Union' is available on the EuropaBio web site.

[i] Timelines according to Reg EC 1829/2003, Art 7 and Council Decision 1999/468/EC Art 5.4.
[ii] 2 months maximum under the new procedure involving the Appeal Committee (for some products under the old procedure involving Council even "without delay").
[iii] The Commission sometimes chooses to submit applications with a positive EFSA safety opinion back to EFSA, based on the rationale that risk assessment requirements evolve quickly and that therefore applications whose risk assessment were concluded several years ago might need an additional EFSA safety opinion. Experience shows that EFSA usually confirms the substance of the earlier assessment. Therefore this document measures the delays from the publication of the initial EFSA opinion for each application.
[iv] Where the application date is before EFSA creation (2002), it refers to the date of application to Member State authorities.
[v] Standing Committee or Regulatory Committee
[vi] Appeal Committee or Council
[vii] 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 applications were added up.
[viii] 33 million tons in soya meal equivalents in the 2008-09 season and four million tons of maize products imported in the 2008-09 season, coming mainly from Brazil, Argentina and the US
[ix] Evaluation of the EU legislative framework in the field of cultivation of GMOs (…) for DG SANCO, European Commission, published in autumn 2011).
http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf; Evaluation report (2011) on approvals for food/ Feed, published by the Commission:
http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf EuropaBio report (2011) "Approvals of GMOs in the European Union":
www.europabio.org/agricultural/positions/approvals-gmos-european-union