



Undue delays in EU authorisation of safe GM crops

As of June 1st 2014, 21 safety tested GM crops are being delayed illegally in the EU for a total of 44 years. Additional unjustifiable delays have been increasing since mid-2013, threatening the security of the EU's food and feed supply.

In a democratic system, regulators should abide by the rules they have decided upon themselves – the EU is not following this principle when it comes to GMOs.

The European Commission has admitted that it regularly fails to abide by the EU's strict laws for authorisation of GM products, by causing illegal delays in approvals of safety-assessed GM crops¹. After the votes by Member States, the Commission has recently been unjustifiably slow to grant a final approval. These procedures following the confirmation of safety by the EU's competent authority take on average 40% of the total time from application to authorisation.

The approval system: steps and timelines

The European Food Safety Authority (EFSA) undertakes an extensive scientific risk assessment for each product submitted for approval. The assessment took on average **29 months** for GM products approved in 2011-2013. If EFSA finds a product as safe as its non-GM counterpart, a political decision to approve it must then be taken. This decision-making phase managed by the European Commission involves EU Member States and takes on average **19 months**. Regular disagreement between the Member States prolongs the process. For other regulated products, such as food additives or pesticides, this process goes a lot faster.

Where the illegal delays occur

EU law requires the European Commission to follow specific timelines²: it has a maximum of 3 months to ask the Member States' representatives to vote on a risk assessed product. If no qualified majority is reached, the Commission has to hold another vote within 2 months. Yet the Commission has formally admitted that it regularly fails to comply with these legal timelines. The General Court of the EU ruled in September 2013: "the European Commission has failed to fulfil its obligations (...) by failing to submit to Council" a GM dossier. In essence, the ruling confirmed that the Commission must respect the legally prescribed processes and timelines, and cannot misuse bureaucratic processes or political arguments to illegally delay the authorisation of a regulated product³.

¹ In Reply to MEP question E-004184/2012: <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-004184&language=EN>

² Timelines according to Reg (EC) 1829/2003, Art 7 and Council Decision 1999/468/EC Art 5.4

³ Pioneer v. Commission (Case T-164/10)

Additional unjustifiable delays

Following the two rounds of voting by Member States, the Commission approves the product following the original positive EFSA opinion. Unprecedented delays of up to **7 months** at this final stage have recently affected product authorisations. For GM products approved in 2011-2013 the statistics showed that this stage could be done in 1 month.

Growing backlog and longer timelines

More GM applications are currently pending in the system (**67**) than were ever approved (**50**). Since 2010, fewer GM crops have been authorised on a yearly basis. **Zero GM products have been approved so far in 2014**. Timelines for import approvals are increasing: **48 months** in the EU (2011-2013), up from 45 months (2004-2010), compared to 30 months on average in the big exporting countries of the Americas.

Effects of the slowing system

Trade: The EU's zero tolerance policy on traces of not yet EU-approved products threatens the trade of certain commodities. Even minute traces can cause rejection of entire shipments in spite of no proven safety concerns.

The cost resulting from the rejection of a maize shipment of 50,000 tons is estimated at €25 million. Constant business uncertainties for traders add to the figure. A study published by the Commission estimates that, in a worst-case scenario, "the total cost to the (EU) economy would be € 9.6 billion."⁴

Innovation: The unworkable authorisation system also delays or prevents innovation and access to safe new technologies.

Consumer confidence: The more the EU institutions fail to implement the law and illegally delay authorisation, the more they undermine public confidence in the regulatory system and nurture unfounded concerns about product safety.

Recommendations for improvement

- **Abide by the rule of law and put pending dossiers to the vote.**
- **Avoid unjustifiable delays before final approval.**

For analysis and suggestions for improvements, see the 2011 reports by the European Commission⁵ and by EuropaBio⁶.

⁴ http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/full-text_en.pdf

⁵ http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm

⁶ <http://www.europabio.org/approvals-gmos-european-union>

Timelines for GM products with a positive EFSA safety opinion and awaiting Commission action as of June 1st 2014:

| PRODUCT(scope) ⁷ | TRAIT, Company | APPLICATION received by EFSA ⁸ | OPINION published by EFSA | FIRST VOTE ⁹ : maximum 3 months for the Commission to schedule. Months (m) and days (d) waiting for the vote. | SECOND VOTE ¹⁰ : maximum 2 months for the Commission to schedule it. Months (m) and days (d) waiting for the vote. | FINAL APPROVAL ¹¹ : No legal deadline Months (m) and days (d) waiting for Commission final approval ¹² |
|--|---|---|---------------------------|--|---|--|
| Applications for food and feed uses, import and processing | | | | | | |
| Maize NK603 (ffip) | herbicide tolerance, Monsanto | 08/2005 | 11/06/2009 | 59 m 21 d and counting | | |
| Maize MON863 (ffip - renewal) | insect resistance, Monsanto | 06/2007 | 30/03/2010 | 50 m 2 d and counting | | |
| Cotton MON531 (ffip - renewal) | insect resistance, Monsanto | 06/2007 | 16/09/2011 | 36 m 16 d and counting | | |
| Cotton MON1445 (ffip - renewal) | herbicide tolerance, Monsanto | 06/2007 | 16/12/2011 | 33 m 16 d and counting | | |
| Cotton MON531xMON1445 (ff - renewal) | insect resistance, herbicide tolerance, Monsanto | 06/2007 | 28/03/2012 | 26 m 4 d and counting | | |
| Cotton MON88913 (ffip) | herbicide tolerance, Monsanto | 04/2007 | 26/02/2014 | 3 m 6 d and counting | | |
| Maize MON87460 (ffip) | drought tolerance, Monsanto | 05/2009 | 15/11/2012 | Voted after 9 m 29 d (13/9/2013) | Voted after 1 m 8 d (21/10/2013) | 7 m 11 d and counting |
| Oilseed Rape GT73 (ffip) (renewal and extension of) | herbicide tolerance, Monsanto | 08/2010 | 12/02/2013 | Voted after 11 m 22 d (21/01/2014) | Voted after 1 m 6 d (27/02/2014) | 3 m 5 d and counting |
| Cotton T304-40 (ffip) | insect resistance, herbicide tolerance, | 04/2011 | 20/06/2013 | Voted after 8 m (20/02/2014) | Voted after 1 m 7 d (27/03/2014) | 2 m 5 d and counting |
| Maize T25 (ffip) (renewal) | herbicide tolerance, Bayer CropScience | 07/2007 | 03/10/2013 | Voted after 6 m 20 d (24/04/2014) | 1 m 9 d and counting | |
| Soybean MON87708 (ffip) | herbicide tolerance, Monsanto | 02/2011 | 03/10/2013 | Voted after 6 m 20 d (24/04/2014) | 1 m 9 d and counting | |
| Soybean MON87705 (ffip) | herbicide tolerance, increased oleic acid, Monsanto | 02/2010 | 30/10/2012 | Voted after 18 m 23 d (23/05/2014) | 8 d and counting | |
| Soybean 305423 (ffi) | Herbicide tolerance, high-oleic acid, | 06/2007 | 18/12/2013 | Voted after 5 m 5 d (23/05/2014) | 8 d and counting | |
| Soybean BPS-CV127-9 (ffip) | herbicide tolerance, BASF | 01/2009 | 17/01/2014 | Voted after 4 m 6 d (23/05/2014) | 8 d and counting | |
| Soybean MON 87769 (ffip) | contains stearidonic acid, Monsanto | 10/2009 | 16/05/2014 | 16 d and counting | | |
| Cotton GHB614 x LLCotton25 (ffip) | herbicide tolerance, Bayer CropScience | 02/2010 | 16/05/2014 | 16 d and counting | | |
| Applications including cultivation in their scope | | | | | | |
| Maize MON810 (ffipc - renewal) | insect resistance, Monsanto | 06/2007 | 30/06/2009 | 59 m 2 d and counting | | |
| Maize GA21 (ffipc) | herbicide tolerance, Syngenta | 07/2008 | 16/12/2011 | 29 m 16 d and counting | | |
| Maize 59122 (ffipc) | insect resistance, herbicide tolerance, Pioneer/Dow | 10/2005 | 26/03/2013 | 14 m 6 d and counting | | |
| Maize Bt11(fpc) | insect resistance, Syngenta | 05/1996 | 19/05/2005 | Voted after 45 m 6 d (25/02/09) | 58 m 7 d and counting | |
| Maize 1507 (c) | insect resistance, Pioneer/Dow AgroSciences | 11/2000 | 03/03/2005 | Voted after 47 m 22 d (25/02/09) | Voted after 59 m 17 d (11/02/2014) | 3 m 20 d and counting |
| Accumulated months (m) and days (d) of processing a product file per column | | | | 499 m 3 d | 117 m 24 d | |
| Accumulated months (m) and days (d) of legally prescribed timelines per column | | | | 19 delayed product files x 3 months = 57 months | 2 delayed product files x 2 = 4 months | |
| ACCUMULATED ILLEGAL DELAY¹³ | | | | ~ 528 months = ~ 44 years | | |

TABLE COLOUR CODES:

- Illegally delayed votes
- Votes held after an illegal delay
- Unjustifiably delayed final approvals after votes (regularly achievable in one month)
- Votes held within the legally prescribed timelines
- Votes currently achievable within the legally prescribed timelines

⁷ This list does not include products which have been put on hold following an agreement between the applicant and the European Commission.

⁸ Where the application date is before EFSA creation (2002), it refers to the date of application to Member State authorities.

⁹ Standing Committee or Regulatory Committee, Article 7(1) of Regulation 1829/2003

¹⁰ Appeal Committee or Council

¹¹ Pursuant to the new Comitology Regulation 182/2011 the European Commission is no longer obliged to adopt a final decision in case of disagreement in the Standing Committee and in the Appeal Committee ("shall adopt" is replaced by 'may adopt').

¹² The statistics from product approvals in 2011-2013 show that final approval usually came within 1 month after the second comitology vote.

¹³ The accumulated illegal delay was calculated by deducting the legally prescribed timelines for each vote (3 or 2 months) from the total time for processing the pending applications since the publication of the respective EFSA opinion.