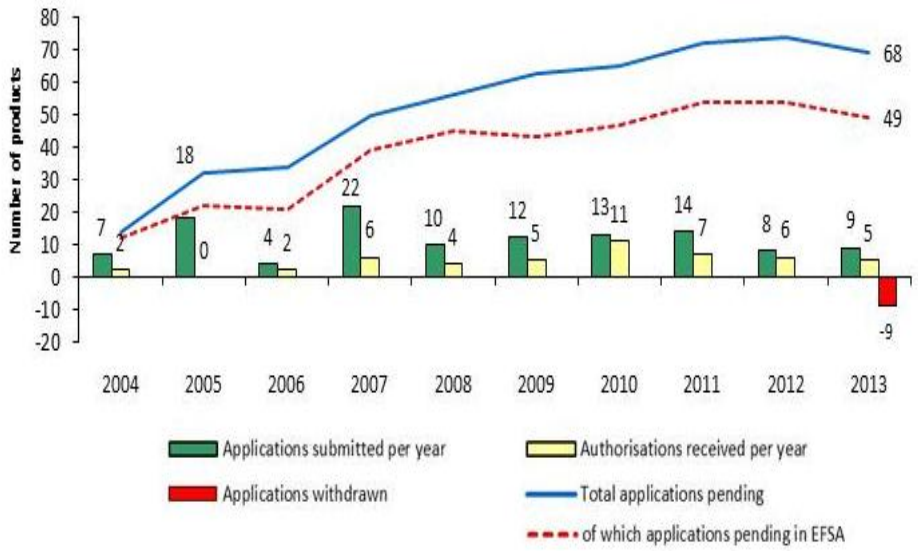
Approvals of GM Crops in the EU
January 2014 update

- Fewer products have been authorised each year since 2010 – see fig. 1
- Timelines to authorisation are increasing – see fig. 2
- Legally prescribed timelines for 16 applications are not being met by the Commission – see annex.

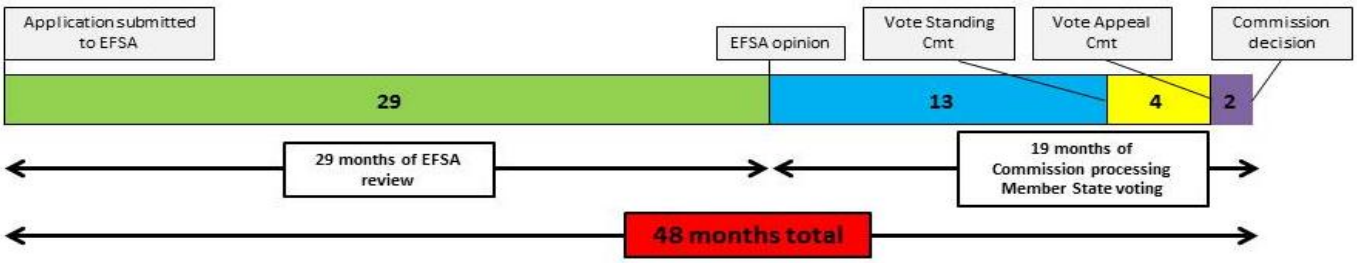
➢ **The system is slowing down, which increases the likelihood of trade disruptions.**

Fig 1: Fewer GM authorisations each year



As of 1 January 2014, a total of 50 GM events are authorised in the EU. 68 GMO application dossiers are pending in the authorisation system (blue line), of which 49 are waiting for a scientific opinion from EFSA (red line) and **19 have received the EFSA opinion** but are currently waiting for Commission/ Member State action (see annex)**.** Each year in the history of the system, more applications entered the system than authorisations were received. Since 2010, fewer GMO application dossiers have been authorised each year.

Fig 2: Longer timelines to authorisation in 2011-2013



For GM food/feed products approved in 2011-2013, the EU authorization process took on average 48 months in total, of which **19 months** were spent on processing and voting-related procedures after EFSA positive opinion. In 2004-2011 the average overall duration was 45 months, of which 16 months post EFSA. GM cultivation dossiers have been pending for many more years in the authorisation system (see annex), which illustrates the dysfunctionality of the approval process for cultivation in the EU.

Impacts of the slowing system

- **Trade:** EU approval timelines are increasingly out of synchrony with timelines in the main producer countries of agricultural commodities. The EU's zero tolerance policy on not yet EU-approved products means that certain commodities cannot be traded, to the extent that even traces of such products can cause entire shipments to be rejected, despite the product not posing any safety concern. The cost resulting from rejection of a maize shipment of 50,000 tons is estimated at €25 million, however less visible trade disturbances and constant business uncertainty for traders add to the cost. 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. "*[1] A DG AGRI in-house study concludes that potential trade disruptions *"could become more severe, more frequent, and affect more products"*[2].
- **Innovation:** Unworkable product authorisation systems also delay or prevent innovation and access to new technologies.
- **Consumer confidence:** The more the EU institutions do not implement applicable law, but unduly delay authorisation processes, the more they undermine public confidence in the regulatory system and in the authorities; and nurture unfounded concerns about product safety.

Background Information

The EU authorization procedure

The EU authorization procedure for GM products is one of the most stringent in the world. First, EFSA carries out an extensive scientific risk assessment. If it finds the product as safe as its non-GM counterpart, it delivers a favorable opinion for its authorization. In the next phase, a political decision must be taken which involves the Commission and the Member States.

Major developments in 2013

- Unprecedented delays at the very final stage in the process (after Member State votes in two committees) were incurred by the European Commission on certain product authorisations for import. The General Court of the EU concluded twice that the Commission has mismanaged the approval process. On 26 September 2013, it ruled that "the European Commission has failed to fulfil its obligations (…) by failing to submit to Council" a GM dossier and added that "the Commission cannot, in a dilatory manner, repeatedly request opinions from EFSA".
- The Commission adopted a new Implementing Regulation[3] in April 2013, which formally introduces risk assessment requirements which are scientifically unjustified, ultimately sliding towards an unworkable regulatory system.
- EFSA published three inconclusive opinions on GM applications in 2013, mainly due to difficulties in information flow between EFSA and applicants.
- The continued complete dysfunctionality of the approval process for cultivation in the EU has been illustrated by the withdrawal of 9 cultivation applications.

Analysis and suggestions for improvement

- For analysis and suggestions for improvements, please consult the reports by the Commission[4] and by EuropaBio[5], both published in 2011. For more recent data, see the EuropaBio report from 2013[6].

[1] Study on the Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products" (December 2010, on behalf of DG AGRI) http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/full-text_en.pdf
[2] Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production", DG AGRI http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf
[3] Implementing Regulation No 503/2013: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF
[4] http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm
[5] http://www.europabio.org/approvals-gmos-european-union
[6] http://www.europabio.org/positions/failures-eu-authorisation-system-gmos-causes-impacts-and-solutions

Annex: Undue delays in the risk management phase - status 01/01/2014

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

In the framework of the EU's strict approval procedure, once EFSA has published its scientific opinion, EU legislation requires the European Commission to stick to specific timelines[1]: It has a maximum of 3 months to ask the Member State representatives to vote (2nd 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[2] (right column). However, the Commission has formally admitted that it regularly fails to comply with legal timelines when it comes to GM authorisations[3], a practice which the General Court has confirmed to be illegal.

Product	Trait, company	Application received by EFSA[4]	Publication of EFSA Opinion	Months (m) and days (d) waiting for the EC to schedule 1st vote[5]: max 3 months	Months (m) and days (d) waiting for the EC to schedule 2nd vote[6] : max 2 months
Applications for food/ feed/ imports					
Cotton MON1445 (ffip - renewal)	herbicide tolerant, Monsanto	06/2007	16/12/2011	24m 16d & counting	
Cotton MON531 (ffip - renewal)	insect resistant, Monsanto	06/2007	16/09/2011	27m 16d & counting	
Cotton MON531xMON1445 (ff - renewal)	insect res., herbicide tol., Monsanto	06/2007	28/03/2012	21m 04d & counting	
Cotton T304-40 (ffip)	insect res., herbicide tol., Bayer	04/2011	20/06/2013	6m 12d & counting	
Maize MON863 (ffip - renewal)	insect res., Monsanto	06/2007	30/03/2010	45m 02d & counting	
Maize MON87460 (ffip)	drought tol., Monsanto	05/2009	15/11/2012	vote after 09m 29d	Vote after 01m 09d
Maize T25 (ffip) (renewal)	herbicide tol., Bayer	07/2007	03/10/2013	02m 28d & counting	
Oilseed Rape GT73 (ffip - renewal)	herbicide tol., Monsanto	06/2007	15/12/2009	48m 17d & counting	
Oilseed Rape GT73 (ffip) (extension of scope)	herbicide tol., Monsanto	08/2010	12/02/2013	10m 20d & counting	
Soybean 305423 (ffi)	altered for healthier oil, Pioneer	06/2007	04/12/2013	01m 25d & counting	
Soybean MON87705 (ff)	altered for healthier oil, herbicide tol., Monsanto	02/2010	17/12/2013	01m 04d & counting	
Soybean MON87708 (ffip)	herbicide tol., Monsanto	02/2011	03/10/2013	02m 28d & counting	
Applications including cultivation in their scope					
Maize 1507 (c)	insect res., Pioneer/Dow AgroSciences	11/2000	03/03/2005	vote after 47m 22d	58 m 07 d & counting
Maize 59122 (ffc)	insect res., herbicide tol., Pioneer/Dow AgroSciences	10/2005	26/03/2013	09m 06d & counting	
Maize Bt11 (ipc)	insect res., Syngenta	05/1996	19/05/2005	vote after 45m 06d	58 m 07 d and counting
Maize GA21 (ffipc)	herbicide tol., Syngenta	07/2008	16/12/2011	24m 16d & counting	
Maize MON810 (ffipc - renewal)	insect res., Monsanto	06/2007	30/07/2009	53m 02d & counting	
Maize NK603 (ffipc)	herbicide tol., Monsanto	08/2005	11/06/2009	54m 21d & counting	
Soybean MON 40-3-2 (c)	herbicide tol., Monsanto	11/2005	21/06/2012	18m 11d & counting	
Accumulated undue delay per column				455 m 25 d	117 m 23 d
ACCUMULATED UNDUE DELAY[7]				573 m 18 d = 48 years	

[1] Timelines according to Reg (EC) 1829/2003, Art 7 and Council Decision 1999/468/EC Art 5.4.
[2] 2 months maximum under the new procedure involving the Appeal Committee (for some products under the old procedure involving Council even "without delay").
[3] Reply to MEP question E-004184/2012: http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-004184&language=EN. Given the General Court's confirmation that "the Commission cannot, in a dilatory manner, repeatedly request opinions from EFSA", 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 delay).
[4] Where the application date is before EFSA creation (2002), it refers to the date of application to Member State authorities.
[5] Standing Committee or Regulatory Committee
[6] Appeal Committee or Council
[7] 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.