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The European Association for Bioindustries

Time for the Commission to Authorize Safe GMO Imports

Unprecedented delays risk trade disruptions and threaten animal feed supplies - January 2015

- **Safe products should be allowed onto the market**. European livestock farmers should be allowed to use safe animal feed of their choice, while European consumers should have access to biotech products with health benefits.
- **Yet, for over a year, the European Commission has put on hold the authorization** of genetically modified (GM) crops for import, despite confirmation from the European Food Safety Authority (EFSA) that these products are as safe as conventional crops. Today 58 GM applications for import are pending in the EU system, of which 18 have already completed the EFSA risk assessment.
- **This matters because Europe is highly dependent on imports of GM crops**. Without these imports, the competitiveness and viability of our livestock farming sector will be jeopardised.

"A suicidal situation for European growth"

European farmers' organization Copa-Cogeca, together with various actors from the food and feed supply chain, has urged the Commission not to further delay the authorization of safe GM commodity imports, warning they are essential for the livestock industry. "Any further delays by the EU Commission will result in a suicidal situation for European growth"[1].

Commission studies: delays threaten livestock

Even studies by and on behalf of the European Commission confirm that, as a result of unduly delayed GMO import authorizations, trade disruptions *"could become more severe, more frequent, and affect more products". "The total cost to the economy would be € 9.6 billion".* There could be a *"sharp increase in the beef meat price"*, and poultry production could *"drop to 29 % below the baseline"*[2].

What has changed?

Undue delays are not new[3], but the Commission's failure to take the final decision on the authorization of products that have completed the entire authorization process started in the autumn of 2013. No explanation has been given for this failure to act and EuropaBio is not aware of any major external changes: product safety is confirmed[4] and has not changed, and neither has the voting behavior of Member States. Public acceptance is arguably improving[5].

Innovation & trade need legal certainty

The purpose of a pre-market product approval system with an extensive risk assessment is to ensure that new products are allowed on the market as long as they are safe. Refusing market access for safe products makes the authorization system dysfunctional. Would citizens accept if they were withheld a driving license, despite having passed their driving test? Legal certainty, including in regulatory systems, is essential for all industries, when they decide on which continents to provide new jobs and products. Trading partners are expected to base any barriers to trade on objective grounds.

No rule of law?

The last *de facto* moratorium on GM authorizations in the EU (1998 to 2004) was ruled illegal by the WTO in 2006, because it had led to undue delays. At the very least, the Commission must stick to democratically agreed European law, but this has not been the case when it comes to GMOs[6]. For example, the 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 crops[7].

Review of GM decision making process

Therefore, the review of the decision making process applied to GMOs announced by President Juncker in 2014 should focus on making the system functional again, by properly implementing the existing European legislation.

EU no longer dictates what world farmers grow

Globally, farmers growing GM crops outnumber all European farmers, and they grow these crops on a surface bigger than the entire EU arable land. Almost all soya – the prime sources of proteins for European livestock – is provided by South and North American countries, where GM technology adoption is over 90% (93% in the USA, 89% in Brazil and 100% in Argentina). Although the EU is highly dependent on such imports, China is now by far the biggest importer, ahead of the EU[8].

Failure to act threatens also conventional imports

Due to the EU policy of zero tolerance to GMOs not yet approved in the EU (even where their safety is confirmed by EFSA), shipments of various conventional commodities containing traces of EU-unapproved events, are also affected. One hundred per cent purity cannot be technically guaranteed in agriculture, which is why numerous legal thresholds exist to cater for admixtures and impurities, including some with hazardous properties[9] – but none are accepted for safe GMOs!

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[1] Copa-Cogeca, Coceral, Fediol, Fefac, Uecbv and A.v.e.c statement
[2] DG AGRI : Economic Impact of Unapproved GMOs on EU Feed Imports (2007); Study on the Implications of Asynchronous GMO Approvals (on behalf of DG AGRI (2010).
[3] Selected sources: WTO, EC ("system could be more efficient"), USDA, EuropaBio 2011, 2013(1), 2013(2), 2014(1), 2014(2)
[4] EFSA opinions; EuropaBio: Factsheet Product Safety (2013); What people say about GMO safety (2014)
[5] Frankenfine - Attitudes to genetically modified food seem to be changing, *The Economist,* Nov 2014; "Green Biotechnology: Are Germans changing their minds?", Forum Grüne Vernunft 2013; "The use and value of polling to determine public opinion on GMOs in Europe", GM Crops and Food, 2013

[6] Legal Considerations Related to the Authorization (..) of GM Crops in the EU, D Abrahams, *Bio-Science Law Review*
[7] In Reply to MEP question E-004184/2012
[8] EuropaBio Factsheet Trade in Agriculture (2013)
[9] including, for instance, highly carcinogenic mycotoxins

A growing backlog of applications for imports

- The EU approval system for GM imports includes a thorough safety assessment, followed by a political process involving the European Commission and Member States[10].
- As of January 1st 2015, more GM applications are pending in the system than were ever authorized[11].
- Zero GM products were approved in 2014, and each year since 2010, fewer and fewer GM crops were authorized[12].
- As of January 1st 2015, 58 GM applications for import are pending in the system, of which 18 are already confirmed by EFSA to be as safe as conventional crops (see table below).
- Timelines from submission to approval of GM import dossiers are increasing substantially from under 4 years to over 6 years[13].
- The 12 products at the bottom of the list below have been awaiting the Commission's final decision, on average, for 6 months following the second vote by Member States, compared to an average of 1 month between 2011 and mid-2013.
- In case no authorisations are granted within the next two years, the number of safety assessed pending dossiers can reasonably be expected to grow from currently 18 to more than 60[14].

Status & Delays of risk assessed GM import dossiers pending in the EU system as of January 1st 2015

PRODUCT[15]	TRAIT, Company	EFSA[16]		FIRST VOTE: maximum 3 months for EC to schedule[17].	SECOND VOTE: maximum 2 months for EC to schedule[18].	FORMAL ADOPTION average duration of 1 month (before late 2013)
		SUBMISSION	OPINION			
6 safety assessed products pending for Member State votes:						
Cotton MON15985	insect resistance, Monsanto	05/2007	28/07/2014	5m 4d and counting		
Cotton MON531xMON1445 (renewal)	insect resistance, herbicide tolerance, Monsanto	06/2005	28/03/2012	33m 4d and counting		
Cotton MON1445	herbicide tolerance, Monsanto	06/2007	16/12/2011	36 m 16d and counting		
Cotton MON531 (renewal)	insect resistance, Monsanto	06/2007	16/09/2011	39m 16d and counting		
Maize MON863 (renewal)	insect resistance, Monsanto	06/2007	30/03/2010	57m 2d and counting		
Soybean MON 87769	healthier oil, Monsanto	10/2009	16/05/2014	Voted after 6m 23d (9/12/2014)	23d and counting	
12 safety assessed and voted products pending for formal adoption by the European Commission:						
Cotton MON88913	herbicide tolerance, Monsanto	04/2007	13/03/2014	Voted after 7m 11d (24/10/2014)	Voted after 1m 4d (28/11/2014)	1m 4d and counting
Cotton GHB614 × LLCotton25	herbicide tolerance, Bayer CropScience	02/2010	16/05/2014	Voted after 5m 8d (24/10/2014)	Voted after 1m 4d (28/11/2014)	1m 4d and counting
Oilseed Rape MON 88302	herbicide tolerance, Monsanto	09/2011	17/06/2014	Voted after 4m 7d (24/10/2014)	Voted after 1m 4d (28/11/2014)	1m 4d and counting
Maize NK603	herbicide tolerance, Monsanto	08/2005	11/06/2009	Voted after 60m 12d (23/06/2014)	Voted after 17d (10/07/2014)	5m 22d and counting
Maize T25 (renewal)	herbicide tolerance, Bayer CropScience	07/2007	03/10/2013	Voted after 6 m 20 d (24/04/2014)	Voted after 1m 17d (10/06/2014)	6m 22d and counting
Soybean MON87708	herbicide tolerance, Monsanto	02/2011	03/10/2013	Voted after 6 m 20 d (24/04/2014)	Voted after 1m 17d (10/06/2014)	6m 22d and counting
Soybean MON87705	herbicide tolerance, healthier oil, Monsanto	02/2010	30/10/2012	Voted after 18 m 23 d (23/05/2014)	Voted after 18d (10/06/2014)	6m 22d and counting
Soybean 305423	herbicide tolerance, healthier oil, Pioneer	06/2007	18/12/2013	Voted after 5 m 5 d (23/05/2014)	Voted after 18d (10/06/2014)	6m 22d and counting
Soybean BPS-CV127-9	herbicide tolerance, BASF	01/2009	17/01/2014	Voted after 4 m 6 d (23/05/2014)	Voted after 18d (10/06/2014)	6m 22d and counting
Cotton T304-40	insect resistance, herbicide tolerance, Bayer CropScience	04/2011	20/06/2013	Voted after 8 m (20/02/2014)	Voted after 1m 7d (27/03/2014)	9 m 5d and counting
Oilseed Rape GT73 (renewal, extend scope)	herbicide tolerance, Monsanto	08/2010	12/02/2013	Voted after 11 m 22 d (21/01/2014)	Voted after 1m 6d (27/02/2014)	10 m 5d and counting
Maize MON87460	drought tolerance, Monsanto	05/2009	15/11/2012	Voted after 9 m 29 d (13/9/2013)	Voted after 1m 8d (21/10/2013)	14 m 11d and counting
AVERAGE TIME for processing a product file				**17m 8d**	**1m**	**6m 11d**
AVERAGE time from submission to 1 January 2015				**76 months**		

[10] Overview of the process: EuropaBio infographic
[11] As of January 2015, 48 GM applications for import have been approved, and 59 are pending. (If cultivation dossiers are included, in total 50 approvals to date compared to 66 pending dossiers).
[12] 11 approvals in 2010, 7 in 2012, 6 in 2012, 5 in 2013, 0 in 2014
[13] 45 months on average for products authorized 2004-1111, 48 months on average for dossiers authorized 2011-13. The 18 pending risk assessed products listed below were submitted, on average, 76 months ago.
[14] 40 import dossiers are currently pending in EFSA. For products approved in 2011-13, EFSA took 29 months on average from submission to the publication of a scientific opinion *(see also EuropaBio, Undue delays in EU authorisation of safe GM crops, June 2014)*. For the 18 safety assessed products currently pending, EFSA took on average 51 months to deliver an opinion
[15] This list does not include products which have been put on hold following an agreement between the applicant and the European Commission.
[16] Where the application date is before EFSA creation (2002), it refers to the date of application to Member State authorities.
[17] Standing Committee, Article 7(1) of Regulation 1829/2003; months (m) and days (d) waiting for the vote since delivery of the EFSA opinion
[18] Appeal Committee; months (m) and days (d) waiting for the vote since the vote in the Standing Committee