

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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Voluntary - Public

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## EU-28

**Post:** Brussels USEU

## European Commission Authorizes Ten Genetically Modified Organisms

### Report Categories:

Biotechnology - GE Plants and Animals

SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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### Report Highlights:

On July 26, 2019, the European Commission (EC) leadership approved/renewed nine genetically modified organism (GMO) biotech events for food/feed/fiber uses and one biotech ornamental cut flower. The timeframe for the EC's GMO regulatory authorization process is lengthy with one of the events awaiting approval since 2011. The EC pattern is to approve groups of events during either the December holiday season or in the middle of the summer months.

**General Information:**

On July 26, 2019, the EC authorized/approved ten biotech events, seven for food/feed/fiber uses (cotton GHB614xLLCotton25xMON1598, maize 5307, maize MON 87403, maize 4114, maize MON87411, maize Bt11xMIR162x1507xGA21, soybean MON87751), renewed two authorizations for food/feed (oilseed rape Ms8xRf3 and maize 1507xNK603) and one carnation as an ornamental cut flower. The authorizations are for imported products only, not cultivation, and valid for a ten-year period. Any products developed from these imported events will be subject to the EU's labeling and traceability regulations.

Under the GMO Directive, all events for import or domestic cultivation must initially undergo a comprehensive risk assessment and scientific review by the European Food Safety Authority (EFSA). A positive determination by EFSA typically results in the EC proposing authorization of the event(s) to the European Union member states who vote on each event in the Standing Committee on Plants, Animals, Food and Feed (PAFF) comprised of member state experts and government officials. A positive vote in the PAFF requires a qualified majority, but that threshold is always not met resulting in an inconclusive decision and a subsequent appeal. The Appeals Committee then reviews those biotech events invariably resulting in a “no opinion” determination, placing the final decision with the College of Commissioners, an entity representing the top leadership of the EC. The College can either approve or deny the proposed biotech events. The aforementioned process resulted in the College approving the following events:

<b>Product Code</b>	<b>Variety</b>	<b>Application to EFSA</b>	<b>EFSA’s Completeness Check</b>	<b>EFSA’s Published Opinion</b>	<b>PAFF Vote</b>	<b>Appeal Committee vote</b>
Bt 11 x MIR 162 x 1507 x GA 21	Maize	9/7/2010	6/14/2012	9/1/2016	1/14/2019	2/22/2019
MON 87411	Maize	2/10/2015	8/17/2015	6/28/2018	1/14/2019	2/22/2019
4114	Maize	11/27/2014	3/30/2015	5/24/2018	1/14/2019	2/22/2019
MON 87751	Soybean	10/8/2014	1/22/2015	6/20/2018	3/7/2019	4/11/2019
1507 x NK603 (Renewal)	Maize	12/22/2016	5/12/2017	7/25/2018	3/7/2019	4/11/2019
GHB 614 x LL Cotton 25 x MON 15985	Cotton	2/25/2011	7/15/2015	4/19/2018	12/3/2018	1/14/2019
MON 87403	Maize	6/26/2015	2-Oct-15	3/21/2018	12/3/2018	1/14/2019

MS8, RF3, MS8xRF3 (Renewal)	Rape	9/9/2016	10/21/2016	11/28/2017	12/3/2018	1/14/2019
5307	Maize	4/12/2011	6/21/2011	11/4/2018	12/3/2018	1/14/2019

+ one carnation approved