

Annex 3

2019 Annual report on general surveillance of genetically modified organisms from FEDIOL



Brussels, 12/07/2019

[REDACTED]

[REDACTED]
EuropaBio
Avenue de l'Armée 6
1040 Brussels

Subject: 2019 annual report on general surveillance of genetically modified organisms

Dear [REDACTED],

We are responding to EuropaBio and its member companies regarding the general surveillance of genetically modified organisms (GMOs) that have been authorised for placing on the market in the EU according to Directive 2001/18/EC and/or Regulation (EC) No 1829/2003. We recognise our organisation's role in the supply chain to facilitate the notification by operators of any observed unanticipated adverse effects of GMOs on human and animal health or the environment.

In view of the above, FEDIOL has undertaken the necessary steps to

- Inform and remind its member organisations and companies on an annual basis
 - to monitor for potential unanticipated adverse effects
 - that, in the framework of their management or safety standards (ISO, HACCP, ...), procedures must be in place and implemented to limit losses and spillage of viable GMOs and to routinely eradicate adventitious populations on their premises
 - to inform and remind their own member companies of this requirement
 - to report back any adverse effect reported to them to the European trade associations
- Report to the authorisation holders directly or via EuropaBio
 - at least annually, regardless whether an adverse effect was observed or not
 - immediately any adverse effects reported to them.

For the authorised GMO(s) listed in the Annex, FEDIOL has alerted its members to the product and safety information made available by the consent holder(s) via EuropaBio's operator website, including any information regarding the general surveillance of the listed product(s).

FEDIOL has been collating reports of potential adverse effects resulting from the placing on the market of these products, which may have come to the attention of its members.

To date FEDIOL confirm(s) that throughout the reporting period and based on their annual reminder to its member organisations and companies, no observed adverse effects have been reported from the monitoring by their members.

Yours sincerely,

[REDACTED]

List of GMOs authorised for placing on the market in the EU in accordance with Directive 2001/18/EC and/or Regulation (EC) No 1829/2003, and for which general surveillance is required (List provided by EuropaBio):

Company Development Code	Unique Identifier Commission	Decision for Authorisation the Placing on the Market of the GMO	Type of Product	Trade Name
MON 87427 x MON 89034 x 1507 x MON 88017 x 59122	MON-87427-7 x MON-89034-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	20181219 Implementing Commission Decision 2018/2046	Maize	SmartStax with the Roundup Hybridization System
MON 87427 x MON 89034 x NK603 and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603	MON-87427-7 x MON-89Ø34-3 x MON-ØØ6Ø3-6	20180803 Commission Implementing Decision 2018/1111	Maize	Genuity® VT Double PRO® with Roundup® Hybridization System
GA21	MON-ØØØ21-9	20180803 Commission Implementing Decision (EU) 2018/1112	Maize	Agrisure® GT
1507 x 59122 x MON 810 x NK603 and eight related GM maize combining two or three of the single events	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 and eight related combinations of the single events	20180803 Commission Implementing Decision 2018/1110/EU	Maize	
59122	DAS-59122-7	20180803 Commission Implementing Decision (EU) 2018/1109 amended by 20190206 Commission Implementing Decision (EU) 2019/241	Maize	Herculex® RW Rootworm Protection Maize
FG72 x A5547-127	MST-FGØ72-2 x ACS-GMØØ6-4	20171221 Commission Implementing Decision (EU) 2017/2451	Soybean	
1507	DAS-Ø15Ø7-1	20171221 Commission Implementing Decision 2017/2452 amended by 20190206 Commission Implementing Decision (EU) 2019/241	Maize	Herculex® I Insect Protection maize
DAS-68416-4	DAS-68416-4	20171221 Commission Implementing Decision 2017/2449 amended by 20190206 Commission Implementing Decision (EU) 2019/239	Soybean	Enlist™ Soybean
MON 88302 x MS8 x RF3	MON-883Ø2-9 x ACS-BNØØ5-8 x ACS-BNØØ3-6	20171221 Commission Implementing Decision 2017/2453 see 20190628 Commission Implementing Decision (EU) 2019/1167	Oilseed rape	

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305423 x 40-3-2	DP-305423-1 x MON-04032-6	20171221 Commission Implementing Decision 2017/2448	Soybean	Plenish® High oleic soybean
DAS-44406-6	DAS-44406-6	20171221 Commission Implementing Decision 2017/2450 amended by 20190206 Commission Implementing Decision (EU) 2019/239	Soybean	Enlist E3™ Soybean
DAS-40278-9	DAS-40278-9	20170704 Commission Implementing Decision (EU) 2017/1212 amended by 20190206 Commission Implementing Decision (EU) 2019/239	Maize	Enlist™ Maize
281-24-236 x 3006-210-23 x MON 88913	DAS-24236-5x DAS-21023-5x MON-88913-8	20170704 Commission Implementing Decision 2017/1211 amended by 20190206 Commission Implementing Decision (EU) 2019/239	Cotton	WideStrike® Flex cotton
MON 810	MON-00810-6	20170704 Commission Implementing Decision (EU) 2017/1207	Maize	YieldGard® Corn Borer
Bt11 x 59122 x MIR604 x 1507 x GA21 and twenty related GM maize combining two, three or four different single GM events	SYN-BT011-1 x DAS-59122-7 x SYN-IR604-5 x DAS-01507-1 x MON-00021-9	20170704 Commission Implementing Decision (EU) 2017/1209	Maize	Agrisure Viptera® 3111 (highest order stack)
GHB119	BCS-GH005-8	20170704 Commission Implementing Decision (EU) 2017/1208	Cotton	
Bt11 x MIR162 x MIR604 x GA21 and ten related GM maize combining two or three different single GM events	SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x MON-00021-9	20160916 Commission Implementing Decision (EU) 2016/1685 Amended by 20190111 Commission Implementing Decision (EU) 2019/60	Maize	Agrisure® 3122 (highest order stack)
MON 87705 x MON 89788	MON-87705-6 x MON-89788-1	20160722 Commission Implementing Decision 2016/1217	Soybean	Vistive® Gold
MON 87708 x MON 89788	MON-87708-9 x MON-89788-1	20160722 Commission Implementing Decision 2016/1216	Soybean	Roundup Ready 2 Xtend™
FG72	MST-FG072-2	20160722 Commission Implementing Decision (EU) 2016/1215	Soybean	

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NK603 x T25	MONØØ6Ø3-6 x ACS-ZMØØ3-2	20151204 Commission Implementing Decision 2015/2279	Maize	
MON 87427	MON-87427-7	20151204 Commission Implementing Decision 2015/2281	Maize	
MON 87769	MON-87769-7	20150424 Commission Implementing Decision 2015/686	Soybean	
T304-40	BCS-GHØØ4-7	20150424 Commission Implementing (EU) Decision 2015/699	Cotton	
MON 87708	MON-877Ø8-9	20150424 Commission Implementing Decision 2015/700	Soybean	
GT73	MON-ØØØ73-7	20150424 Commission Implementing Decision 2015/701/EC	Oilseed rape	Roundup Ready® Oilseed Rape
MON 88913	MON-88913-8	20150424 Commission Implementing Decision 2015/688	Cotton	Genuity® Roundup Ready® Flex Cotton
305423	DP-3Ø5423-1	20150424 Commission Implementing Decision 2015/698	Soybean	Plenish® High oleic soybeans
MON 87705	MON-877Ø5-6	20150424 Commission Implementing Decision 2015/696	Soybean	
GHB614 x LLCotton25	BCS-GHØØ2-5xACS-GHØØ1-3	20150424 Commission Implementing Decision (EU) 2015/690	Cotton	GlyTol® LibertyLink®
MON 88302	MON-883Ø2-9	20150424 Commission Implementing Decision 2015/687	Oilseed rape	TruFlex™ Canola
NK603	MON-ØØ6Ø3-6	20150424 Commission Implementing Decision 2015/684	Maize	Roundup Ready® Corn 2
CV127	BPS-CV127-9	20150424 Commission Implementing Decision (EU) 2015/691	Soybean	Cultivance®
T25	ACS-ZMØØ3-2	20150424 Commission Implementing Decision (EU) 2015/697	Maize	LibertyLink®
MON 15985	MON-15985-7	20150424 Commission Implementing Decision 2015/685	Cotton	Genuity® Bollgard® II Cotton
MON 87460	MON 8746Ø-4	20150424 Commission Implementing Decision 2015/683	Maize	DroughtGard® Hybrids

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MON89034 x 1507 x NK603	MON-89Ø34-3x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6.	20131106 Implementing Commission Decision 2013-648-EU amended by 20190206 Commission Implementing Decision (EU) 2019/240	Maize	Genuity® PowerCore™
MON 89034 x 1507 x MON 88017 x 59122	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	20131106 Commission Implementing Decision 2013 -650-EU amended by 20190206 Commission Implementing Decision (EU) 2019/240	Maize	Genuity® SmartStax®
MS8 x RF3	ACS-BNØØ5-8 ACS-BNØØ3-6 ACS-BNØØ5-8x ACS-BNØØ3-6	20130625 Commission Implementing Decision 2013/327/EU	Oilseed rape	InVigor® Hybrid Oilseed Rape Ms8/Rf3
MIR162	SYN-IR162-4	20121018 Commission Implementing Decision 2012/651/EU amended by 20190111 Commission Implementing Decision (EU) 2019/60	Maize	Agrisure Viptera®
MON 87701 x MON 89788	MON-877Ø1-2 x MON-89788-1	20120628 Commission Implementing Decision 2012/347/EU	Soybean	Intacta RR2 PRO®
40-3-2	MON-Ø4Ø32-6	20120210 Commission Implementing Decision 2012/82/EC	Soybean	Roundup Ready® Soybean
356043	DP-356Ø43-5	20120210 Commission Implementing Decision 2012/84/EU	Soybean	Optimum® GAT® soybean
MON87701	MON-877Ø1-2	20120210 Commission Implementing Decision 2012/83/EU	Soybean	Insect Protected Soybean
A5547-127	ACS-GMØØ6-4	20120210 Commission Implementing Decision 2012/81/EU	Soybean	LibertyLink® Soybean
281-24-236 x 3006-210-23	DAS-24236-5x DAS-21Ø23-5	20111222 Commission Implementing Decision 2011/891/EU amended by 20190206 Commission Implementing Decision (EU) 2019/239	Cotton	WideStrike Insect Protection
GHB614	BCS-GHØØ2-5	20110617 Commission Implementing Decision 2011/354/EU	Cotton	GlytoITM
Bt11	SYN-BTØ11-1	20100728 Commission Implementing Decision 2010/419/EU	Maize	Agrisure® CB/LL

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		amended by 20190111 Commission Implementing Decision (Eu) 2019/60		
1507 x 59122	DAS-Ø15Ø7-1xDAS-59122-7	20100728 Commission Implementing Decision 2010/432/EU From 3/08/2018 see 20180803 Commission Implementing Decision 2018/1110/EU	Maize	Herculex® XTRA
59122 x 1507 x NK603	DAS-59122-7xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6	20100728 Commission Implementing Decision 2010/428/EU From 3/08/2018 see 20180803 Commission Implementing Decision 2018/1110/EU	Maize	Herculex® XTRA x Roundup Ready® Corn 2
MON 88017 x MON 810	MON-88Ø17-3 x MON-ØØ81Ø-6	20100728 Commission Implementing Decision 2010/429/EU	Maize	YieldGard® VT Triple®
MIR604	SYN-IR6Ø4-5	20091130 Commission Implementing Decision 2009/866/EC amended by 20190111 Commission Implementing Decision (EU) 2019/60	Maize	Agrisure® RW
MON 89034	MON-89Ø34-3	20091030 Commission Implementing Decision 2009/813/EC	Maize	YieldGard VT® PRO
MON 88017	MON-88Ø17-3	20091030 Commission Implementing Decision 2009/814/EC	Maize	YieldGard® VT Rootworm/RR2®
59122 x NK603	DAS-59122-7x MON-ØØ6Ø3-6	20091030 Commission Implementing Decision 2009/815/EC ; From 3/08/2018 see 20180803 Commission Implementing Decision 2018/1110/EU	Maize	Herculex® RW x Roundup Ready® Corn 2 Maize
A2704-12	ACS-GMØØ5-3	20080908 Commission Decision 2008/730/EC	Soybean	LibertyLink Soybean
T45	ACS-BNØØ8-2	20090310 Commission Implementing Decision 2009/184/EC	Oilseed rape	LibertyLink® Oilseed Rape
MON 89788	MON-89788-1	20081204 Commission Implementing Decision 2008/933/EC	Soybean	Roundup Ready 2 Yield® Soybean
LLCotton 25	ACS-GHØØ1-3	20081029 Commission Implementing Decision 2008/837/EC	Cotton	LibertyLink Cotton

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NK603 x MON 810	MON-ØØ6Ø3-6x MON-ØØ81Ø-6	20071024 Commission decision 2007/701/EC	Maize	YieldGard® Corn Borer with Roundup Ready®
1507 x NK603	DAS-Ø15Ø7-1xMON-ØØ6Ø3-6	20071024 Commission decision 2007/703/EC amended by 20190206 Commission Implementing Decision (EU) 2019/241	Maize	Herculex® I x Roundup Ready® Corn 2 maize