

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

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

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

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

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

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