

Annex 3
**2020 Annual report on general surveillance of genetically
modified organisms from FEDIOL**

Brussels, 17/07/2020

[REDACTED]
EuropaBio
Avenue des Arts 53
1000 Brussels

Subject: 2020 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 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and 14 related combinations of the single events | MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7 × DAS-40278-9 and 14 related combinations of the single events | 20191128 Commission Implementing Decision (EU) 2019/2086 | Maize | SmartStax® Enlist™ Maize |
| MON 89034 × 1507 × NK603 × DAS-40278-9 and three related combinations of the single events | MON-89034-3 × DAS-01507-1 × MON-00603-6 × DAS-40278-9 and three related combinations of the single events | 20191128 Commission Implementing Decision (EU) 2019/2085 | Maize | PowerCore™ Enlist™ Maize |
| MZHGOJG | SYN-000JG-2 | 20191128 Commission Implementing Decision (EU) 2019/2080 | Maize | |
| Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 | SYN-BT011 × SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1 × MON-00021-9 | 20191128 Commission Implementing Decision (EU) 2019/2087 | Maize | Agrisure Duracade® 5222 |
| MON 87411 | MON-87411-9 | 20190726 Commission Implementing Decision (EU) 2019/1308 | Maize | |
| GHB614 × LLCotton25 × MON 15985 | BCS-GH002-5 × ACS-GH001-3 × MON-15985-7 | 20190726 Commission Implementing Decision (EU) 2019/1302 | Cotton | |
| 5307 | SYN-05307-1 | 20190726 Commission Implementing Decision (EU) 2019/1303 | Maize | Agrisure Duracade® |
| MON 87403 | MON-87403-1 | 20190729 Commission Implementing Decision (EU) 2019/1307 | Maize | |
| MON 87751 | MON-87751-7 | 20190726 Commission Decision (EU) 2019/1309 | Maize | |
| Bt11 × MIR162 × 1507 × GA21 | SYN-BT011-1 × SYN-IR162-4 × DAS-01507-1 × MON-00021-9 | 20190726 Commission Implementing Decision (EU) 2019/1305 | Maize | Agrisure Viptera® 3220 |
| 4114 | DP-004114-3 | 20190726 Commission Implementing Decision (EU) 2019/1304 | Maize | |
| MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 | MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7 | 20181219 Implementing Commission Decision (EU) 2018/2046 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | SmartStax with the Roundup Hybridization System |
| MON 87427 × MON 89034 × NK603 and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603 | MON-87427-7 × MON-89034-3 × MON-00603-6 | 20180803 Commission Implementing Decision (EU) 2018/1111 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | Genuity® VT Double PRO® with Roundup® Hybridization System |

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|---|---|--|-----------------|--|
| 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 (EU) 2018/1110 | 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 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Soybean | |
| 1507 | DAS-Ø15Ø7-1 | 20171221 Commission Implementing Decision (EU) 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 (EU) 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 (EU) 2017/2453 see 20190628 Commission Implementing Decision (EU) 2019/1167 | Oilseed rape | |
| 305423 x 40-3-2 | DP-3Ø5423-1 x MON-Ø4Ø32-6 | 20171221 Commission Implementing Decision (EU) 2017/2448 | Soybean | Plenish® High oleic soybean |
| DAS-44406-6 | DAS-444Ø6-6 | 20171221 Commission Implementing Decision (EU) 2017/2450 amended by 20190206 Commission Implementing Decision (EU) 2019/239 | Soybean | Enlist E3™ Soybean |
| DAS-40278-9 | DAS-4Ø278-9 | 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-21Ø23-5x MON-88913-8 | 20170704 Commission Implementing Decision (EU) 2017/1211 amended by 20190206 Commission Implementing Decision (EU) 2019/239 | Cotton | WideStrike® Flex cotton |

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|---|---|---|-----------------|--|
| MON 810 | MON-ØØ81Ø-6 | 20170704 Commission Implementing Decision (EU) 2017/1207 and 20131106 Commission Implementing Decision 2013/649/EU both amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | 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-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 | 20170704 Commission Implementing Decision (EU) 2017/1209 | Maize | Agrisure Viptera® 3111 (highest order stack) |
| GHB119 | BCS-GHØØ5-8 | 20170704 Commission Implementing Decision (EU) 2017/1208 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Cotton | |
| Bt11 x MIR162 x MIR604 x GA21 and ten related GM maize combining two or three different single GM events | SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9 | 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-877Ø5-6 x MON-89788-1 | 20160722 Commission Implementing Decision (EU) 2016/1217 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | Vistive® Gold |
| MON 87708 x MON 89788 | MON-877Ø8-9 x MON-89788-1 | 20160722 Commission Implementing Decision (EU) 2016/1216 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | Roundup Ready 2 Xtend™ |
| FG72 | MST-FGØ72-2 | 20160722 Commission Implementing Decision (EU) 2016/1215 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Soybean | |
| NK603 x T25 | MONØØ6Ø3-6 x ACS-ZMØØ3-2 | 20151204 Commission Implementing Decision (EU) 2015/2279 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | |
| MON 87427 | MON-87427-7 | 20151204 Commission Implementing Decision (EU) 2015/2281 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | |
| MON 87769 | MON-87769-7 | 20150424 Commission Implementing Decision (EU) 2015/686 amended | Soybean | |

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|-------------------------------------|------------------------------|--|-----------------|-------------------------------------|
| | | by 20190918 Commission Implementing Decision (EU) 2019/1579 | | |
| T304-40 | BCS-GHØØ4-7 | 20150424 Commission Implementing Decision (EU) 2015/699 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Cotton | |
| MON 87708 | MON-877Ø8-9 | 20150424 Commission Implementing Decision (EU) 2015/700 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | |
| GT73 | MON-ØØØ73-7 | 20050831 Commission Decision 2005/635/EC and 20150424 Commission Implementing Decision 2015/701/EC amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Oilseed rape | Roundup Ready® Oilseed Rape |
| MON 88913 | MON-88913-8 | 20150424 Commission Implementing Decision (EU) 2015/688 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Cotton | Genuity® Roundup Ready® Flex Cotton |
| 305423 | DP-3Ø5423-1 | 20150424 Commission Implementing Decision (EU) 2015/698 | Soybean | Plenish® High oleic soybeans |
| MON 87705 | MON-877Ø5-6 | 20150424 Commission Implementing Decision (EU) 2015/696 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | |
| GHB614 × LLCotton25 | BCS-GHØØ2-5xACS-GHØØ1-3 | 20150424 Commission Implementing Decision (EU) 2015/690 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Cotton | GlyTol® LibertyLink® |
| MON 88302 | MON-883Ø2-9 | 20150424 Commission Implementing Decision (EU) 2015/687 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Oilseed rape | TruFlex™ Canola |
| NK603 | MON-ØØ6Ø3-6 | 20150424 Commission Implementing Decision (EU) 2015/684 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | Roundup Ready® Corn 2 |
| BPS-CV127-9 | BPS-CV127-9 | 20150424 Commission Implementing Decision (EU) 2015/691 | Soybean | Cultivance® |

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|--|--|---|-----------------|--------------------------------------|
| T25 | ACS-ZMØØ3-2 | 20150424 Commission Implementing Decision (EU) 2015/697 amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Maize | LibertyLink® |
| MON 15985 | MON-15985-7 | 20150424 Implementing Commission Decision (EU) 2015/685 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Cotton | Genuity® Bollgard® II Cotton |
| MON 87460 | MON 87460-4 | 20150424 Commission Implementing Decision (EU) 2015/683 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | DroughtGard® Hybrids |
| MON89034 × 1507 × NK603 | MON-89Ø34-3×DAS-Ø15Ø7-1×MON-ØØ6Ø3-6. | 20131106 Implementing Commission Decision 2013/648/EU amended by 20190206 Commission Implementing Decision (EU) 2019/240 | Maize | Genuity® PowerCore™ |
| MON 89034 × 1507 × MON 88017 × 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, RF3 and MS8 × RF3 | ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6 | 20130625 Commission Implementing Decision 2013/327/EU amended by 20190710 Commission Implementing Decision (EU) 2019/1195 and by 20190726 Commission Implementing Decision (EU) 2019/1301 | 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 × MON-89788-1 | 20120628 Commission Implementing Decision 2012/347/EU amended by 20190918 Commission Implementing Decision 2019/1579 | Soybean | Intacta RR2 PRO® |
| 40-3-2 | MON-Ø4Ø32-6 | 20120210 Commission Implementing Decision 2012/82/EU amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | Roundup Ready® Soybean |
| 356043 | DP-356Ø43-5 | 20120210 Commission Implementing Decision 2012/84/EU | Soybean | Optimum® GAT® soybean |

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|--|------------------------------|---|-----------------|------------------------------|
| MON87701 | MON-877Ø1-2 | 20120210 Commission Implementing Decision 2012/83/EU amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Soybean | Insect Protected Soybean |
| A5547-127 | ACS-GMØØ6-4 | 20120210 Commission Implementing Decision 2012/81/EU amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Soybean | LibertyLink® Soybean |
| 281-24-236 × 3006-210-23 | DAS-24236-5xDAS-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 Decision 2011/354/EU amended by 20190710 Commission Implementing Decision (EU) 2019/1195 | Cotton | Glytol™ |
| Bt11 | SYN-BTØ11-1 | 20100728 Commission Implementing Decision 2010/419/EU amended by 20190111 Commission Implementing Decision (EU) 2019/60 | Maize | Agrisure® CB/LL |
| MON 88017 × MON 810 | MON-88Ø17-3 × MON-ØØ81Ø-6 | 20100728 Commission Implementing Decision 2010/429/EU amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | 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 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | YieldGard VT® PRO |
| MON 88017 | MON-88Ø17-3 | 20091030 Commission Implementing Decision 2009/814/EC amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | YieldGard® VT Rootworm/RR2® |
| A2704-12 | ACS-GMØØ5-3 | 20191128 Commission Implementing Decision (EU) 2019/2084 | Soybean | LibertyLink Soybean |
| T45 | ACS-BNØØ8-2 | 20191128 Commission Implementing Decision (EU) 2019/2081 | Oilseed rape | LibertyLink® Oilseed Rape |

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|------------------------------------|------------------------------|---|-----------------|---|
| MON 89788 | MON-89788-1 | 20191128 Commission Decision (EU) 2019/2083 | Soybean | Roundup Ready 2 Yield® Soybean |
| LLCotton25 | ACS-GHØ1-3 | 20191128 Commission Implementing Decision (EU) 2019/2082 | Cotton | LibertyLink Cotton |
| NK603 × MON 810 | MON-ØØ6Ø3-6x MON-ØØ81Ø-6 | 20181219 Commission decision (EU) 2018/2045 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Maize | YieldGard® Corn Borer with Roundup Ready® |
| 1507 × NK603 | DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 | 20190726 Commission Implementing decision (EU) 2019/1306 | Maize | Herculex® I x Roundup Ready® Corn 2 maize |
| MON 531 x MON 1445 | MON-ØØ531-6 x MON-Ø1445-2 | 20150424 Commission Decision (EU) 2015/695 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Cotton | Bollgard® with Genuity® Roundup Ready® Cotton |
| MON 531 | MON-ØØ531-6 | 20150424 Commission Decision (EU) 2015/689 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Cotton | Bollgard® Cotton |
| MON 1445 | MON-Ø1445-2 | 20150424 Commission Decision (EU) 2015/693 amended by 20190918 Commission Implementing Decision (EU) 2019/1579 | Cotton | Roundup® Ready Cotton |