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Report Name: MARA Issues New and Renewed GE Biosafety Certificates

Country: China - People's Republic of

Post: Beijing

Report Category: Biotechnology and Other New Production Technologies, Planting Seeds, Grain and

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Report Highlights:

On January 13, 2023, the Ministry of Agriculture and Rural Affairs (MARA) announced the issuance of new and renewed biosafety certificates for genetically engineered (GE) events. The announcement follows the conclusion of the National Biosafety Committee (NBC) meeting in December 2022 and includes eight new and two renewed certificates issued for GE crops approved for import as processing materials and six new and 32 renewed certificates for domestic GE crop cultivation and production. Notably, the new certificates approved for import processing include first time approvals for GE alfalfa and sugarcane as well as several events that began the application process more than a decade ago. The validity period of new and renewed biosafety certificates is five years.

On January 13, 2023, MARA announced that additional new and renewal biosafety certificates were issued for several GE events. The announcement includes eight new and two renewed certificates issued for GE crops approved for import as processing materials. The certificates include three new GE cotton events developed by BASF, Bayer, and Corteva, two renewed GE cotton events developed by BASF, one new GE rapeseed event developed by Corteva, two new GE sugarcane events developed by Brazil Sugarcane Technology Center, and two new GE alfalfa events developed by Bayer.

The tranche of new approvals is notable in several ways. First, the biosafety certificates for GE sugarcane and alfalfa mark the first time the People's Republic of China (PRC) approved GE varieties of either commodity for import. Second, the volume of new approvals for import (eight in total) issued is unprecedented, especially following several years when the NBC typically approved only one or two new events. Lastly, the rapeseed and alfalfa approvals bring to a conclusion three of the longest outstanding foreign developer applications, each having spanned more than a decade.

The announcement also included renewals for 32 biosafety certificates for domestic cultivation/production, including 29 GE cotton events and three animal vaccines, and six new approvals for cultivation/production, including two GE corn events, one GE soybean event, and three animal vaccines. All new and renewed biosafety certificates are valid for five years.

The two lists (in Chinese) are available on the MARA webpage for agricultural biotechnology:

The MARA list of approved import certificates is available at: http://www.moa.gov.cn/ztzl/zjyqwgz/spxx/202301/P020230113566699597851.pdf

The MARA list of new and renewed cultivation/production certificates is available at: http://www.moa.gov.cn/ztzl/zjyqwgz/spxx/202301/P020230113566699966911.pdf

This report contains an unofficial translation of the list of the 10 new and renewed biosafety certificates issued to biotech crops approved for import as processing materials and the list of 38 new and renewed biosafety certificates for domestic cultivation and production. For additional information on China's biosafety certificates and approval process, please see the 2022 China: Agricultural Biotechnology Annual Report.



Table 1. China: Biotech Crops Approved for Import as Processing Materials in January 2023

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
1	Trans-cry1Ab and bar gene insect resistant and herbicide tolerant cotton T304-40 (renewal)	April 10, 2014	BASF	Jan. 5, 2023-Jan.4, 2028
2	Trans- cry2Ae and bar gene insect resistant and herbicide tolerant cotton GHB119 (renewal)	April 10, 2014	BASF	Jan. 5, 2023-Jan.4, 2028
3	Trans- 2mepsps and hppdPfW336-1Pa gene herbicide tolerant cotton GHB811 (new)	January 5, 2023	BASF	Jan. 5, 2023-Jan.4, 2028
4	Trans- dmo and bar gene herbicide tolerant cotton MON88701 (new)	January 5, 2023	Bayer CropScience	Jan. 5, 2023-Jan.4, 2028
5	Trans- aad-12 gene herbicide tolerant cotton DAS-81910-7 (new)	January 5, 2023	Corteva	Jan. 5, 2023-Jan.4, 2028
6	Trans-c gat4621gene herbicide tolerant rapeseed DP73496(new)	January 5, 2023	Pioneer International Seed Company*	Jan. 5, 2023-Jan.4, 2028
7	Trans- cry1Ab gene insect resistant sugarcane H7-1 CTC175-A (new)	January 5, 2023	Brazilian Sugar Cane Technology Center	Jan. 5, 2023-Jan.4, 2028
8	Trans- cry1Ab gene insect resistant sugarcane CTC91087-6 (new)	January 5, 2023	Brazilian Sugar Cane Technology Center	Jan. 5, 2023-Jan.4, 2028
9	Trans- cp4epsps gene herbicide tolerant alfalfa J101 (new)	January 5, 2023	Bayer CropScience Land O' Lakes	Jan. 5, 2023-Jan.4, 2028
	Trans- cp4epsps gene herbicide tolerant alfalfa J163 (new)	January 5, 2023	Bayer CropScience Land O' Lakes	Jan. 5, 2023-Jan.4, 2028

^{*}FAS China Comment: At the time of original application, the event was submitted by Pioneer International Seed Company. The event now belongs to Corteva.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

 Table 2. China: Biotech Crops/Events Approved for Cultivation/Production in January 2023

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
1	Trans-crylAb/crylAc insect-resistant cotton Han No. 505 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
2	Trans-crylAb/crylAc insect-resistant cotton Han No. 656 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
3	Trans-crylAb/crylAc insect-resistant cotton Han No. 686 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
4	Trans-crylAb/crylAc insect-resistant cotton Han No. 818 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
5	Trans-crylAb/crylAc insect-resistant cotton Han Za No. 301 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
6	Trans-crylAb/crylAc insect-resistant cotton Han Za No. 13 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
7	Trans-crylAb/crylAc insect-resistant cotton Han Za No. 14 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
8	Trans-crylAb/crylAc insect-resistant cotton Han Za No. 15 (renewal)	Handan Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
9	Trans-crylAc insect-resistant cotton Yunza 208F1	Hebei Shenniu Agricultural Technology Co., Ltd.	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
10	Trans- <i>cry1Ab/cry1Ac</i> gene insectresistant cotton Nongxing No. 1 (renewal)	Huimin County Luyou Agricultural Technology Co., Ltd.	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
11	Trans- <i>cry1Ab/cry1Ac</i> insect-resistant cotton Miaobao No. 21 (renewal)	Shandong Miaobao Seed Industry Co., Ltd.	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
12	Trans- crylAc insect-resistant cotton KRZ06 (renewal)	Shandong Yinxing Seed Industry Co., Ltd.	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
13	Trans-crylAc gene insect-resistant cotton Yinxing No. 8 (renewal)	Shandong Yinxing Seed Industry Co., Ltd.	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
14	Trans-crylAc gene insect-resistant cotton H11160 (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
15	Trans-crylAc gene insect-resistant cotton H12188 (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
16	Trans-crylAc gene insect-resistant cotton H13 (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
17	Trans-crylAc gene insect-resistant cotton H172 (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
18	Trans-crylAc gene insect-resistant cotton H4R (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
		Sciences		
19	Trans-crylAc gene insect-resistant cotton H171 (renewal)	Cotton Research Institute of Shanxi Academy of Agricultural Sciences	Yellow River Basin Inland Northwest	Jan. 5, 2023-Jan.4, 2028
20	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Zhongmiansuo 99007 (renewal)	Cotton Research Institute of Chinese Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
21	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Zhongmiansuo 99011(renewal)	Cotton Research Institute of Chinese Academy of Agricultural Sciences	Yellow River Basin	Jan. 5, 2023-Jan.4, 2028
22	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Jinhumian 128 (renewal)	Hubei Jinhu Crop Research Institute	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
23	Trans- cry1Ab/cry1Ac gene insect- resistant cotton A9001 (renewal)	Hunan Qicheng Agricultural Technology Co., Ltd.	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
24	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Xiangfengmian No. 5 (renewal)	Hunan Qicheng Agricultural Technology Co., Ltd.	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
25	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Xiangzamian No. 15 (renewal)	Hunan Institute of Cotton Science	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
26	Trans- cry1Ab/cry1Ac gene insect-	Hunan Xiangza Seed Industry	Yangtze River	Jan. 5, 2023-Jan.4, 2028

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
	resistant cotton Jinza No. 1 (renewal)	Co., Ltd.	Basin	
27	Trans- cry1Ab/cry1Ac gene insect- resistant cotton H116 (renewal)	Huazhong Agricultural University	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
28	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Longfumian No.316 (renewal)	Wuhan Longfukang Agricultural Development Co., Ltd.	Yangtze River Basin	Jan. 5, 2023-Jan.4, 2028
29	Trans- cry1Ab/cry1Ac gene insect- resistant cotton Huamian 3097 (renewal)	Huazhong Agricultural University	Inland Northwest	Jan. 5, 2023-Jan.4, 2028
30	Trans- cry1Ab, cry1F and cp4epsp gene insect-resistant and herbicide tolerant maize BFL4-2 (new)	Yuanlongping Agricultural High Technology Company; Institute of Biotechnology, Chinese Academy of Agricultural Sciences	North Spring Corn Area	Jan. 5, 2023-Jan.4, 2028
31	Trans- maroACC gene herbicide tolerant maize CC-2 (new)	China Forestry Seed Group Co., Ltd. China Agricultural University	North Spring Corn Area	Jan. 5, 2023-Jan.4, 2028
32	Trans- cry1Ab/vip3Da gene insectresistant soybean CAL16 (new)	Shanghai Academy of Agricultural Sciences	South Soybean Area	Jan. 5, 2023-Jan.4, 2028
33	Recombinant Newcastle Disease Virus Live Vector Vaccine A-NDV-LX/I4 Expressing Type VII F and HN Genes	Yangzhou University	N/A	Jan. 5, 2023-Jan.4, 2028

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
	(renewal)			
34	Recombinant Escherichia coli subunit vaccine expressing brucellosis gene BL21 (pRSETB-Bluv) (renewal)	Qingdao Mingqin Biotechnology Co., Ltd.	N/A	Jan. 5, 2023-Jan.4, 2028
35	Recombinant turkey herpesvirus rHVT-HA/Re-6 expressing the HA gene of H5 subtype avian influenza virus (renewal)	Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences	N/A	Jan. 5, 2023-Jan.4, 2028
36	Live vector vaccine of turkey herpesvirus expressing chicken infectious bursal disease virus VP2 gene recombinant HVT-IBD (new)	Shuoteng Company	N/A	Jan. 5, 2023-Jan.4, 2028
37	Recombinant plasmid nucleic acid vaccine pIHNch-G expressing rainbow trout infectious hematopoietic necrosis virus G gene (new)	Heilongjiang Fisheries Research Institute, Chinese Academy of Fishery Sciences Pearl River Fisheries Research Institute, Chinese Academy of Fishery Sciences	N/A	Jan. 5, 2023-Jan.4, 2028
38	Recombinant Porcine Pseudorabies Virus Live Vector Vaccine Deleting TK, gI, gE, 11K and 28K Genes PRV- TK-/gI-/gE-/11K-/28K (new)	Pulike Biological Engineering Co., Ltd.	N/A	Jan. 5, 2023-Jan.4, 2028

Attachments:

No Attachments.