

Voluntary Report – Voluntary - Public Distribution

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Report Name: New and Renewed Biosafety Certificates Issued - May 2024

Country: China - People's Republic of

Post: Beijing

Report Category: Biotechnology - Plants and Animals, Planting Seeds, Biotechnology and Other New Production Technologies

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Report Highlights:

On May 8, 2024, the Ministry of Agriculture and Rural Affairs (MARA) announced the issuance of new and renewed biosafety certificates for genetically engineered (GE) and gene-edited events. The announcement includes the first ever gene-edited wheat and corn as well as a GE corn event for domestic cultivation and processing. Also approved were four renewed and six new biosafety certificates for genetically modified microorganisms (GMMs) and 51 renewed biosafety certificates for GE cotton for domestic cultivation and processing. No new or renewed biosafety certificates for GE events for import as processing materials were issued. The validity period of new and renewed biosafety certificates is five years.

Summary:

On May 8, 2024, MARA announced the issuance of new and renewed biosafety certificates for genetically engineered (GE) and gene-edited events. The announcement includes biosafety certificates for the first ever gene-edited wheat event (developed by Qi-Biodesign Biotechnology Company and the Institute of Genetic and Developmental Biology of China Academy of Sciences) and the first ever gene-edited corn event (developed by Shandong Bellagen Biotechnology Company) for domestic cultivation. These latest approvals of gene-edited events bring the PRC's total approved gene-edited events for domestic cultivation to five following recent approvals of three gene-edited soybean events.

Biosafety certificates were also issued for one GE corn event (developed by Beijing Origen Seed Co., Ltd., Institute of Biotechnology, Chinese Academy of Agricultural Sciences, and Beijing Boai Yuanshang Biotechnology Co., Ltd.) for domestic cultivation and processing, four renewed and six new biosafety certificates for genetically modified microorganisms (GMMs) - three for animal vaccines, two for biopharmaceuticals, and one for feed additives use, and, 51 renewed biosafety certificates for GE cotton for domestic cultivation and processing. No new or renewed biosafety certificates for GE events for import as processing materials were issued. The validity period of new and renewed biosafety certificates is five years.

After obtaining a biosafety certificate developers must also obtain a variety registration for their seeds and a seed production and operation license before seeds can be planted for commercial production. For more information, please see GAIN Report [Inaugural Genetically Modified Corn and Soybean Variety Registration List Published](#) and [China Issued First Batch of Genetically Engineered Corn and Soybean Seed Production and Operation Licenses](#).

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

The MARA list of Gene-Edited Events Approved for Cultivation/Processing is available [here](#);

The MARA list of Biotech Crops Approved for Domestic Cultivation and Processing is available [here](#);

The MARA list of Biotech Events Approved for Cultivation and Processing (GMMs for Animal Use) is available [here](#);

The MARA list of Biotech Crops Approved for Domestic Cultivation and Processing (GE cotton renewal) is available [here](#).

This report contains an unofficial translation of the above-mentioned lists except for the GE cotton renewal list. For additional information on China's biosafety certificates and approval process, please see the [2023 China: Agricultural Biotechnology Annual Report](#)

Table 1. China: Gene-Edited Events Approved for Cultivation/Processing in May 2024

No.	Event	Developer	Valid Area	Biosafety Certificate Validity
1	Mutated Br2 gene to improve yield traits maize 179AC19-13-13 (new approval)	Shandong BellaGen Biotechnology Co., Ltd.	National	May 7, 2024-May 6, 2029
2	Mutated TaMLO-A1, TaMLO-B1, TaMLO-D1 and TaMLOX genes in disease-resistant wheat MLO-KNRNP (new approval)	Qi-Biodesign Biotechnology Company Limited the Institute of Genetic and Developmental Biology, China Academy of Sciences	National	May 7, 2024-May 6, 2029

Table 2. China: Biotech Events Approved for Cultivation and Processing (GMMs for Animal Use) in May 2024

No.	Event	Developer	Type	Biosafety certificate validity
1	Bovine infectious rhinotracheitis virus vaccine IBRVΔgG/ΔTK lacking TK and gG genes (renewal)	Huazhong Agricultural University	Vaccine	May 7, 2024-May 6, 2029
2	Replication-deficient recombinant adenovirus (type 5) live vector vaccine pAdeQuick-FMDA expressing bovine foot-and-mouth disease virus (type A) P12A3C gene (renewal)	Jiaxing Anyu Biotechnology Co., Ltd.	Vaccine	May 7, 2024-May 6, 2029
3	Replication-deficient recombinant adenovirus (type 5) live vector vaccine	Jiaxing Anyu Biotechnology Co., Ltd.	Vaccine	May 7, 2024-May 6, 2029

No.	Event	Developer	Type	Biosafety certificate validity
	pAdeQuick-FMDO expressing porcine foot-and-mouth disease virus (type O) P12A3C gene (renewal)			
4	Recombinant Lactobacillus casei live vector vaccine pPG-1/EGFP-ps1/L-393 expressing porcine epidemic diarrhea virus ps1 gene (renewal)	Northeast Agricultural University	Vaccine	May 7, 2024-May 6, 2029
5	Recombinant turkey herpes virus live vector vaccine rHVT-VP2 expressing the VP2 gene of chicken infectious bursal disease virus (new approval)	Qingdao Yibang Bioengineering Co., Ltd.	Vaccine	May 7, 2024-May 6, 2029
6	Reverse genetic construction of recombinant porcine epidemic diarrhea virus inactivated vaccine rAJ1102-S2 (new approval)	Huazhong Agricultural University	Vaccine	May 7, 2024-May 6, 2029
7	D-calcium pantothenate expressed by recombinant E. coli K12 (PT06) (new approval)	Heilongjiang Xinhecheng Biotechnology Co., Ltd.	Feed Additives	May 7, 2024-May 6, 2029
8	Live E. coli vaccine Ecoli.aroA-EC34195 lacking aroA gene (new approval)	Zoetis Corporation	Vaccine	May 7, 2024-May 6, 2029
9	Canine alpha interferon expressed by recombinant Pichia pastoris X33/pPICZαA-CaIFN-α (new approval)	Dongguan Bosheng Biotechnology Co., Ltd. Guangzhou Yuanbo Pharmaceutical Technology Co., Ltd.	Biopharmaceuticals	May 7, 2024-May 6, 2029
10	Feline ω interferon expressed by recombinant Pichia pastoris	Dongguan Bosheng Biotechnology Co., Ltd.	Biopharmaceuticals	May 7, 2024-May 6, 2029

No.	Event	Developer	Type	Biosafety certificate validity
	X33/pPICZ α A-FeIFN- ω (new approval)	Guangzhou Yuanbo Pharmaceutical Technology Co., Ltd. Nanjing Weite Animal Pharmaceutical Co., Ltd.		

Table 3. China: Biotech Crops Approved for Domestic Cultivation and Processing in May 2024

No.	Event	Developer	Valid Area	Biosafety Certificate Validity
1	Transfection of cry1Ab, cry3Bb and cp4epsps genes into insect-resistant and herbicide-tolerant corn BBL2-2 (new approval)	Beijing Origen Seed Co., Ltd. Institute of Biotechnology, Chinese Academy of Agricultural Sciences, Beijing Boai Yuanshang Biotechnology Co., Ltd.	National	May 7, 2024-May 6, 2029

Attachments:

No Attachments.