

Order of the Ministry of Agriculture of the People's Republic of China

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The *Decision of the Ministry of Agriculture on Amendment of the Method on Management of Agricultural Genetically Modified Organism Safety Assessment* had been approved in the 4th Executive Meeting of the Ministry of Agriculture held on May 3, 2016. Now, it is publicly released and will be implemented from Oct. 1, 2016.

Han Changfu
Minister

Jul. 25, 2016

Decision of the Ministry of Agriculture on Amendment of the Method on Management of Agricultural Genetically Modified Organism Safety Assessment

The Ministry of Agriculture has decided to make the following amendments towards the *Method on Management of Agricultural Genetically Modified Organism Safety Assessment*:

1. Clause 1 of Article 5 is amended as: "National Agricultural Genetically Modified Organism Safety Committee will be established in accordance with Article 9 of the Regulation. The Committee will be responsible for safety assessment of genetically modified organisms. The Committee will consist of experts of agricultural genetically modified organism research, production, processing, inspection and quarantine, hygiene and environmental protection. Each term of the Committee is five years.
2. Article 6 is amended as: "The unit working on agricultural genetically modified organism research and test is the first person responsible for safety management of agricultural genetically modified organisms. The unit should establish an agricultural genetically modified organism safety team led by the unit's legal representative. The team takes the responsibility to review works of agricultural genetically modified organism safety management and safety assessment application." A new clause is added as Clause 2: "The unit working on agricultural genetically modified organism research and test should define operational procedures of agricultural genetically modified organism test and enhance traceability management of agricultural genetically modified organism test.
3. Article 16 is amended as: "The Ministry of Agriculture accepts applications of agricultural genetically modified organism safety assessment. If accepted, the application should be handed over to the National Agricultural Genetically Modified Organism Committee for safety assessment. The Committee implements agricultural genetically modified organism safety assessment at least twice a year. Upon receipt of the result of safety assessment, the Ministry of Agriculture gives official reply subject

to the *Administrative Permission Law of the People's Republic of China* and the Regulation.

4. Item 3 of Article 17 is deleted and Item 4 is renumbered as Item 3.
5. In Clause 2 of Article 22, "When submitting the application in the previous clause, the unit of test should provide the following materials" is amended as "When submitting the application in the previous clause, the unit of test should provide the following materials required by related safety assessment guidance". A new clause is added as Clause 3: "When applying for production test, the unit should also submit agricultural genetically modified organism sample, reference sample and test method according to the requirements."
6. A new article is added after Article 22: "Within the valid term of agricultural genetically modified organism safety approval, if the unit of test needs to change the place of test, it should report to the Office of Agricultural Genetically Modified Organism Safety Management."
7. Clause 1 of Article 23 is amended as: "If the unit of test proposes to apply for safety certificate after the finish of agricultural genetically modified organism test, it should submit the application to the Office of Agricultural Genetically Modified Organism Safety Management. The *Agricultural Genetically Modified Organism Safety Certificate* will be issued upon the qualification of safety assessment by the National Agricultural Genetically Modified Organism Safety Committee and the approval by the Ministry of Agriculture." In Clause 2, "When submitting the application in the previous clause, the unit of test should provide the following materials" is amended as "When submitting the application in the previous clause, the unit of test should provide the following materials required by related safety assessment guidance". A new item is added as Item 5: "the unit should submit agricultural genetically modified organism sample, reference sample and test method according to the requirements, but except for those that have been submitted according to Article 22 of this Method."
8. Article 25 is amended as: "For agricultural genetically modified organisms introduced from outside the People's Republic of China or exported to the People's Republic of China, corresponding safety assessment materials should be provided according to the *Method on Management of Imported Agricultural Genetically Modified Organism Safety* and agricultural genetically modified organism sample, reference sample and test method should be submitted when applying for safety certificate.
9. Article 26 is amended as: "In accordance with related regulations by the Ministry of Finance and the National Development and Reform Commission, assessment fee and test fee should be paid when applying for agricultural genetically modified organism safety assessment."
10. Article 34 is amended as: "Units working on agricultural genetically modified organism test/production should accept supervision and inspection by competent agricultural authorities and submit summarization report of test /production of the previous year to the competent agricultural authority of the provincial-level and county-level People's Governments of the place where the test/production is carried out.
11. Necessary amendments are made towards the appendices.

The amended *Method on Management of Agricultural Genetically Modified Organism Safety Assessment* is also publicly released.

This Decision will be implemented from Oct. 1, 2016.