Voluntary - Public

Date: 11/27/2018
GAIN Report Number: MX8054

Mexico

Post: Mexico

New Mexican Regulation for GE Risk Assessments

Report Categories:
Biotechnology - GE Plants and Animals
Biotechnology and Other New Production Technologies

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Report Highlights:
The Secretariat of Agriculture Livestock, Rural Development, Fishery and Food (SAGARPA) published a Mexican Official Norm that sets out new requirements for conducting evaluation studies of the risks that experimental trials of genetically engineered organisms might pose to environment, animal, plant or fishery safety.

General Information:

Introduction: The new Mexican Official Norm (NOM-002-SAG-BIO/SEMARNAT-2017) published by SAGARPA on October 30, 2018, sets out new requirements for conducting evaluation studies of the risks that experimental trials of genetically-engineered organisms might pose to environment, animal, plant or fishery safety.

Disclaimer: This summary is based on a *cursory* review of the subject announcement and therefore should not, under any circumstances, be viewed as a definitive reading of the regulation in question, or of its implications for U.S. agricultural export trade interests. In the event of a discrepancy or discrepancies between this summary and the complete regulation or announcement as published in Spanish, the latter shall prevail.

On October 30, 2018, the Secretariat of Agriculture Livestock, Rural Development, Fishery and Food (SAGARPA) published a new Mexican Official Norm (NOM) in the *Diario Oficial* (Federal Register) that establishes the requirements for evaluating risks to environmental, animal, plant, or fishery safety in the experimental trials of genetically-engineered (GE) organisms. The NOM states that the risk evaluation process must analyze each new GE product in a case-by-case manner and must evaluate the possible risk or effects posed by the experimental trials of the GE organism based on scientific methodology.

The new risk assessment process requires the formulation of a science-based risk hypothesis that includes a problem formulation step in which "policy protection goals" are defined. Policy protection goals are elements that must be protected in the release area, i.e., the biological diversity, environmental, animal, or plant health of the release site, in accordance with current legislation and regulations. Because certain policy goals, such as protecting biodiversity, are often too generic or vague to be useful when formulating an environmental risk assessment, the new NOM attempts to translate policy goals into specific, operational objectives, called "final evaluation points." Researchers must identify any specific objects or qualities that are susceptible to possible undesirable changes caused by the release of the GE organism. In the final step of the risk evaluation process, researchers then generate and evaluate proposals for setting biosecurity measures and/or strategies for risk mitigation.

The previous regulation outlining the risk assessment process for the release of GE organisms into the environment had extremely prescriptive data requirements that constrained problem formulation. Poor problem formulation can increase environmental risk because it leads to the collection of superfluous data that may delay or prevent the introduction of environmentally beneficial products. The previous risk analysis process had more than 100 different data requirements, which made it difficult for public institutions or companies to comply fully with the process. The new NOM now requires an effective problem formulation to maximize the possibility of detecting effects that indicate potential risk.

The new NOM states that the process of risk evaluation must include five steps:

1. Identification of possible risks: Possible risks are identified by comparing the GE organism's characteristics to those of its conventional equivalent to determine possible effects on policy

protection goals.

2. Evaluation of possible risk occurrence: This characterization establishes the possible road map of any damage to the protection goals, considering the kind and level of exposure on the end-points.
3. Evaluation of the consequences of the possible risks: Possible risks will be evaluated and characterized based on the magnitude of the temporal or spatial consequences, as well as the reversibility of the effects.
4. Estimation of the risk level: The estimate of the possible risk level will be made based on the correlation of any possible effects and their magnitude. The aim is to characterize the way in which the GE crop and its conventional equivalent affect the same parameters under the same conditions.
5. Risk Management recommendations: This step determines if the experimental release represents an acceptable or manageable risk and defines strategies for the management and monitoring of these possible risks.

The evaluations required in this new NOM are mandatory to obtain a permit for experimental release into the environment of any GE organism. SAGARPA, through the National Health Service, Food Safety and Food Quality (SENASICA), will receive the evaluations included with the applications for permits.

Important Dates

1. Publication Date: October 30, 2018.

2. Effective Date: January 25, 2019 (sixty business days after publication)

Additional Information

It is strongly recommended that applicants review the whole text of the new NOM-002-SAG-BIO/SEMARNAT-2017 to make sure that the evaluations are complete and presented in the specific formats.