



2 July 2020

(20-4591)

Page: 1/1

Committee on Sanitary and Phytosanitary Measures

Original: English

**THE USDA ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S SECURE RULE ON
BIOTECHNOLOGY ([G/SPS/N/USA/3082/ADD.1](#))**

SUBMISSION BY THE UNITED STATES

The following document, received on 26 June 2020, is being circulated at the request of the delegation of the United States.

1.1. In May 2020, the US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) concluded rulemaking to revise 7 CFR part 340 (Part 340) — APHIS' regulations for certain organisms developed using genetic engineering.

1.2. The final rule – known as the SECURE rule – has been notified to the WTO as [G/SPS/N/USA/3082/Add.1](#). Additionally, the United States has provided a briefing to agricultural attaches located in Washington, D.C.

1.3. The final rule reflects major advances in the science of biotechnology during the past 30 years, as well as the considerable regulatory experience accumulated in the last 30 years assessing the plant pest risks of organisms developed using genetic engineering.

1.4. The SECURE rule will ensure the regulations keep pace with the latest scientific and technological advances, reduce regulatory burdens for developers of plants developed using genetic engineering that are unlikely to pose plant pest risks, and ensure that agency resources are better focused on the prevention of plant pest risk.

1.5. It is critical to examine products based on their characteristics, rather than regulating techniques. With a focus on plant characteristics, the SECURE rule exempts from regulation plants with certain modifications that could otherwise have been achieved through conventional breeding and thus are unlikely to pose an increased plant pest risk compared to conventionally bred crops. These include:

- Modifications such as deletions that are based on cellular repair of targeted DNA breaks;
- Targeted single base pair substitutions; or,
- Modifications that mimic variations existing in the plant's gene pool.

1.6. These exemptions enable USDA to better use its resources and scientific expertise as USDA continues working to ensure that new crop varieties developed using genetic engineering are safe for plant health.
