



**MONITORING OF THE USE OF INTERNATIONAL STANDARDS –
CODEX ALIMENTARIUS GUIDELINES FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT
OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS (CAC/GL 45-2003)**

SUBMISSION BY THE UNITED STATES OF AMERICA

The following document, received on 13 November 2020, is being circulated at the request of the Delegation of the United States of America.

1.1. The United States would like to recall the lively exchange of ideas during the November 2019 Thematic Session on Approval Procedures, where we heard how overly burdensome data requirements are leading to unpredictable delays in approval timelines. These delays and burdens have significant adverse effects on agricultural sustainability, trade and innovation.

1.2. During the November discussion, one Member acknowledged that its requirements were indeed very strict but asserted that they were based on Codex standards.

1.3. Today, we would like to highlight the persistent gaps between the regulatory procedures maintained by some Members for approval of genetically engineered (GE) food products and the Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003).

1.4. In 2003, the Codex Alimentarius stated in CAC/GL 45-2003 that, "animal studies cannot readily be applied to testing the risks associated with whole foods", and that, "detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult".

1.5. Despite these limitations, certain Members continue to require these studies to search for unintended effects related to human health or to instill consumer confidence. This is not consistent with Codex Guideline CAC/GL 45-2003, which explicitly states, "Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information".

1.6. We note that some Members have statutory requirements that include whole food animal feeding studies as part of their safety assessment of GE products. One Member recently revised its guidelines for these studies and all applicants were forced to resubmit their studies for pending applications. Finally, another Member requires that studies performed outside its territory be replicated by its own scientists, claiming that its people's dietary habits are different enough to warrant a new study.

1.7. These unnecessary requirements and costly procedures, such as 90-day animal feeding studies, delay the approval of, use of, and trade in useful and demonstrably safe products. The Codex Guidelines highlight the importance of molecular analysis of the plant, compositional analysis of the food, and toxicity and allergenicity analyses of any new proteins in the food as sufficient to determine safety.

1.8. Competent authorities worldwide have successfully evaluated many genetically engineered plant varieties without requiring animal feeding studies.

1.9. We are aware of three separate projects funded by European governments to look at the value of these studies. All three projects concluded that these expensive studies did not meaningfully improve the safety assessment in these cases.

1.10. We strongly encourage Members to eliminate their requirements that rat feeding studies be routinely performed. If the characterization of the food indicates that the available data are sufficient for a thorough safety assessment, requiring feeding studies is not consistent with the international guidelines established by the Codex Alimentarius in 2003.

1.11. Further, we encourage Members to focus data requirements on the information necessary for conducting the safety assessment, and to consider the assessments of other Members that have been conducted according to the Codex guidelines. The [FAO GM Foods Platform](#) contains a useful repository of food safety assessments performed around the world. Countries may wish to consider the context provided by these assessments when performing their own assessments.
