## Regulatory Process for Biotech Products

EΑ

CBI HHS

WS

FONSI

In addition to requirements for licensure of a conventional product, the biotech-derived product is characterized molecularly and shown to have low risk to animal safety, public health, and the environment.

MS can be tested at CVB Lab **Add Test Authorization Number** Reviewer receives IBC Number **IBC Committee** Inactivation, nonviability (if killed product) **LEGEND** = Summary Information Format = Institutional Biosafety Committee = Master Seed = Risk Analysis (SIF + Risk Assessment) = Federal Register Notice = Environmental Assessment = Confidential Business Information-deleted = Health and Human Services: FDA/CDC/NIH = APHIS Wildlife Services

= Finding of No Significant Impact

Biotech Product (>Master Seed or Cell tested by firm) IBC Application → CVB Lead → CVB Director — **SIF** (live SIF review, CVB testing plan \_\_\_\_\_ Laboratory + Reviewer approve MS MS) (if MS + safety studies satisfactory) Risk Assessment review for HHS -WS live or inactivated product **FONSI** SIF **IBC** MS Field Safety Trials (State Animal Health Official Approval) RA FRN

License?