BACKGROUND INFORMATION:

Numerous studies have emerged providing strong evidence that many viruses, including the African swine fever virus, can survive and be transmissible from feed. There are also anecdotal reports that feed from foreign sources, particularly Asia, is produced in a manner that makes it susceptible to contamination. Not all feed mills in the United States (US) pellet the feed they receive, nor are they equipped to do so.

The US swine industry has taken numerous steps to mitigate a viral threat from imported feed because the imported products have not been stopped by regulatory officials. The use of viral mitigants in feed is currently being investigated as well. These mitigants are not licensed for this purpose, and the impact of their use on the acceptability of pork products from swine that consumed mitigated feed needs to be considered.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services, Strategy and Policy unit, in collaboration with the United States Food and Drug Administration and the USDA Codex Office in the USDA Trade and Foreign Agricultural Service, to conduct a risk assessment(s) in accordance with Codex Alimentarius and World Organization for Animal Health (OIE) guidelines on the use of viral mitigants in feed and to determine the potential impact on swine and pork product trade capabilities when mitigants are used to prevent disease introduction.

INTERIM RESPONSE:

USDA appreciates the opportunity to respond and USAHA’s interest in the potential impact on swine and pork product trade capabilities when mitigants are used to prevent disease introduction. While the Food And Drug Administration (FDA) is the lead agency on this issue, USDA and FDA are both informed of ongoing research and interest in using “mitigants” to “control” ASF in animal food. There are currently no substances approved in the United States for this purpose. FDA’s Center for Veterinary Medicine (CVM) is responsible for reviewing new substances used for animals, including animal food and animal drugs.
CVM has committed to an expedited regulatory review process with any sponsor submitting a possible mitigation product to add to animal food that may help address the concerns associated with transmission of ASF through animal food. CVM continues to remain concerned about safety of using unapproved substances for the purpose of ASF control without these mitigants undergoing proper review for safety reasons; the use of non-approved substances can create a false sense of security with producers or feed manufacturers who may prematurely utilize these substances for control of ASF. CVM continues to remain committed to expediting review of potential “mitigants” added to animal food for ASF control.

Because there is no product approved in the U.S. for “control” of ASF in animal food, USDA and FDA do not think it is appropriate to engage in discussions on risk assessments of mitigants. Such a risk assessment would need to focus on safety or risk to animals or an animal’s health, which in part would include use limitations in any “approval.” In addition, the risk assessment would need to assess the risk of importing or domestic production of animal food with a mitigant approved for the purposes of ASF control in the animal food. Both agencies would be willing to engage in discussions on risk assessment in the future based on products that are found to be acceptable by FDA for use in swine food for purposes of controlling ASF. In the interim, USDA is continuing to finalize their expert elicitation which was conducted to evaluate non-animal origin ingredients and potential for these ingredients to serve as a vector for ASF transmission. USDA will provide a summary of the expert elicitation upon completion.

**FINAL RESPONSE:**

USDA, APHIS, VS appreciates the opportunity to respond and USAHA’s interest in the potential impact on swine and pork product trade capabilities when mitigants are used to prevent disease introduction. While the Food and Drug Administration (FDA) is the lead agency on this issue, USDA and FDA are both informed of ongoing research and interest in using mitigants for ASF in animal food. There are currently no substances approved in the United States for this purpose. FDA’s Center for Veterinary Medicine (CVM) is responsible for reviewing new substances used for animals, including animal food and animal drugs.

CVM has committed to an expedited regulatory review process with any sponsor submitting a possible mitigation product to add to animal food that may help address the concerns associated with transmission of ASF through animal food. CVM continues to remain concerned about safety of using unapproved substances for the purpose of ASF control without these mitigants undergoing proper review; the use of non-approved substances can create a false sense of security with producers or feed manufacturers who may prematurely utilize these substances for prevention of ASF. CVM continues to remain committed to expediting review of potential “mitigants” added to animal food for ASF control.

Because there is no product approved in the U.S. for prevention of ASF in animal food, USDA and FDA do not think it is appropriate to engage in discussions on risk assessments of mitigants. Such a risk assessment would need to focus on safety or risk to animals or an animal’s health, which in part would include use limitations in any “approval.” In addition, the risk assessment would need to assess the risk of importing or domestic production of animal food with a mitigant approved for the purposes of ASF prevention in the animal food. Both agencies would be willing to engage in discussions on risk assessment in the future based on products that are found to be acceptable by FDA for use in swine food for purposes of preventing ASF. In the interim, USDA is continuing to finalize their expert elicitation which was conducted to evaluate non-animal origin ingredients and potential for these ingredients to serve as a vector for ASF transmission. USDA will provide a summary of the expert elicitation upon completion.