RESEARCH ABSTRACT

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Risk assessment of feed ingredients of porcine origin as vehicles for transmission of Porcine Epidemic Diarrhea Virus (PEDV)

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Executive Summary

The objective of this project was to assess the likelihood that feed ingredients of porcine origin may function as vehicles of Porcine Epidemic Diarrhea virus (PEDV) transmission via feed. The scope of the assessment included rendered ingredients, ingredients derived through spray drying porcine blood, and ingredients derived by hydrolyzing porcine tissues. The project was coordinated by a multidisciplinary group at the University of Minnesota (UMN) which included expertise in swine health and epidemiology, swine nutrition, food safety risk analysis, and food engineering. The UMN team convened a stakeholder working group that included a range of technical experts from the animal feed industry and swine industry. The stakeholder group was integrally involved in collection of information relevant to the processes being assessed, and participated in regular conference calls, occasional face to face meetings, and email or phone communications as necessary. The stakeholder group also enabled visits of the UMN team to relevant processing sites to observe facilities and operations. An iterative process of information gathering, synthesis and review was used to ensure the details gathered on industry processes were representative of existing operations. The stakeholder group also reviewed the final document.

Recent North American field studies have indicated that both feed ingredients and cross-contamination of feed are potential routes for PEDV transmission. For any feed ingredient, the risk of the release of infective PEDV is a function of: (1) the concentration of PEDV in the raw materials; (2) the virus survival after ingredient processing (3) the survival of virus during post-processing storage and distribution; and 4) the likelihood of post-processing contamination incorporating PEDV into the finished ingredient. As anticipated, data limitations were a significant constraint in this assessment. The approach taken was to acquire data from diverse sources (industry, scientific literature, experimental studies and industry reports), to document likely caveats for the data sources, and to identify priorities for future data acquisition that would enable more robust conclusions. It is noted that most of the data used in the analysis were unavailable at the commencement of the project, and are derived from very recent studies that have yet to be independently replicated.

No data on PEDV contamination of raw materials were available for the rendering and hydrolyzed protein sources. Estimates of PEDV contamination of liquid plasma were available from industry, based on PCR testing of ingredients over time, and were used in quantitative modeling. Flow charts were designed to illustrate the respective processes used to manufacture the ingredients, and to identify points of likely pathogen inactivation. Data on the thermal and other treatments used to inactivate pathogens during processing were obtained from industry sources. Where available, ranges of key variables (e.g., temperature and time) were documented to indicate likely variability in industry practices.

Previously published studies did not enable adequate portrayal of the thermal inactivation kinetics of the virus. To assess the likelihood of PEDV survival in all three ingredient types, we used recent (and as yet unpublished) experimental data on the thermal inactivation kinetics of PEDV characterized by D values [time at a given temperature needed to inactivate 90% (1 log reduction) of virus]. The estimated

D values ranged from 2.71-7.94 min at 120-145°C in complete feed and 2.0-17.7 min at 60-90°C in different matrices (spray-dried plasma, meat meal, bone meal, meat and bone meal, grow finish premix). In general, D values obtained in damp plasma were higher (more time needed to inactivate 1 log) than in other matrices, suggesting a relatively favorable milieu for virus (or RNA) survival. Based on these D-values, the combinations of temperature and time used in the rendering process (115 to 145°C for 30 to 90 min) were estimated to result in 3.7 to 21.9 log reduction in virus. The combinations of temperature and time during the hydrolyzed process (60 to 90°C for 380 to 440 min plus drying for 1 to 25 min at 115°C) were estimated to result in a cumulative inactivation reduction of 50 logs. Consequently, the likelihood of PEDV survival of either the rendering and hydrolyzed protein processes was deemed to be negligible. However, more extensive data on thermal inactivation of PEDV under conditions similar to the processes evaluated is desirable to verify these conclusions.

Unlike for the rendering and hydrolysis processes, additional information on inactivation of PEDV by spray drying became available during the project. Two sources of information were used to assess the likelihood of PEDV survival after spray-drying. For both scenarios, the initial concentration of virus in liquid plasma (3.8 to 7.8 log RNA copies PEDV/mL) was derived from data provided by the industry. Following the same approach used for the rendering and hydrolyzing assessments, for Scenario 1 the experimental D values at 60-80°C in damp plasma (9.6 to 12.1 min) were used to estimate virus thermal inactivation. Exposure of damp plasma to temperatures between 80-84°C for 20-90 s resulted in an estimated viral inactivation between 0.07-0.26 log. For Scenario 2, we used estimates from 2 published studies estimating PEDV inactivation of 4.2 logs when liquid plasma was dried in a laboratory scale spray dryer.

Simulations in Scenario 1 indicated some likelihood of PEDV survival if at least 0.1% of viral RNA in liquid plasma represented viable virus. An important limitation for Scenario 1 is that it models only thermal inactivation in damp spray-dried plasma, but it is known that other inactivation mechanisms occur during spray-drying. Consequently, the simulation presents a very conservative estimate of PEDV inactivation. Simulations in Scenario 2 indicated negligible risk or PEDV survival across all assumptions of virus viability. An important limitation for Scenario 2 is the uncertainty of extrapolating results from a laboratory scale spray dryer to an industrial scale dryer. Further research is advised to explore the relationship between PEDV survival in laboratory scale and commercial scale spray dryers, and to understand which components of the process contribute most to virus inactivation. Better theoretical understanding of the mechanisms of viral inactivation would be helpful to addressing risk management of viruses generally. In line with practices recently adopted in industry, the effect of storage of spray-dried plasma at room temperature (20-22°C) for two weeks was also estimated using published and experimental studies to achieve an additional 3-5 log inactivation. Taking in consideration the post-processing storage step, the risk of PEDV survival after this storage period was estimated to be negligible to low (PEDV survival predicted only if 100% of the virus in raw plasma were viable) for Scenario 1 and negligible for Scenario 2.

To assess the likelihood for post-processing contamination of the finished ingredient with PEDV, site visits were performed at the processing plants for each of the ingredients. Information gathered from

the visits were compared with general Good Manufacturing Procedures (GMP) for food and feed industry. The potential pathways for PEDV cross-contamination identified were related to: 1) personnel movement from raw material areas to finished ingredient areas where virus carriage under footage, clothing and hands could potentially transfer the virus to the finished ingredient; 2) vehicle movement (i.e. skid-steer loaders to outside areas) where contaminated manure carried out by raw material delivery trucks could be picked up by loader vehicles and contaminate the finished ingredient; 3) airflow patterns within the plants where viral particles may be entrapped in the air and move with it, thus there is potential for cross-contamination if the air reaches finished ingredient areas. In general, most of these pathways were categorized as negligible to low due to the low occurrence of these events and the measures taken by the industry. However, rendering plants categorized as 'open facilities' where vehicles (skid-steer loaders) are used to move the finished ingredient, the likelihood for post-processing contamination was low to moderate due to possible cross-contamination that may occur outside the plants and longer virus persistence during winter in contaminated materials.

In summary, the assessments made in this project are constrained by a paucity of specific data on several aspects that are germane to the risk of PEDV transmission in feed ingredients of porcine origin. Available data on thermal inactivation of PEDV indicate that risk of virus surviving the processes of rendering and hydrolysis (peptone production) are negligible. The time and temperature profiles used in spray-drying are much less severe, and therefore, the possibility of virus survival is inherently greater if non-thermal mechanisms are ignored. Overall, currently available data indicate that probability of PEDV surviving the spray-drying process and current commercial storage periods is extremely small. In the course of the project, several data gaps were identified that contributed to the uncertainty. Risk assessment is an iterative process and the findings of this report may be revised in the future if new knowledge becomes available.