The Role of Proactive Risk Assessments in Ensuring Business Continuity in the Swine Industry during an FMD Outbreak

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Abstract
Emerging and reemerging pathogens of food animals, such as Foot and Mouth Disease (FMD) and H5N1 highly pathogenic avian influenza (HPAI), have the potential to disrupt the supply of food commodities. In the event of an FMD outbreak in the United States, permit requests to move pigs and pork products must be supported by risk assessments (3). To prevent disruptions in business continuity, we developed a novel approach toward improving veterinary emergency-response preparedness. Through a public private collaboration that involves industry, USDA APHIS and academia representatives, we assess the routes of exposures and transmission pathways of infectious diseases prior to the occurrence of an outbreak. This approach allows us to develop appropriate and applicable mitigation measures and biosecurity practices that will help control or lessen the impact of a disease outbreak. This methodology could also be employed for specific food borne pathogens

Introduction
Emerging and reemerging pathogens of food animals, such as Foot and Mouth Disease (FMD) and H5N1 highly pathogenic avian influenza (HPAI), have the potential to disrupt the supply of food commodities. A brief disruption in product or animal movements could result in devastating impacts to the industry, as well as serious animal welfare concerns. Proactively evaluating the risks before an outbreak occurs enables timely movement permitting decisions to be made and supports continuity of business.

FMD is a disease of cloven hoofed animals that is highly contagious with a pan continental distribution, evident by the recent outbreaks in Southeast Asia and Africa. Infected animals usually develop blister-like lesions in the oral cavity, mammary gland and inter-digital areas, resulting in lameness and excessive salivation. Susceptible pigs become infected primarily by coming in contact with infected animals and animal products. FMD is not recognized as a zoonotic disease (5). The economic impact of this disease is usually devastating to the agricultural industry and to other closely associated industries. A study by the U.K. National Audit Office estimated the direct cost of the 2001 FMD outbreak to the public and private sector at over $15.22 billion, and the number of animals slaughtered at six million (1). Foot-and-mouth disease was last reported in the U.S. in 1929, thus there is an existing large pool of naïve animals in the U.S. In addition to the ravaging effects of the disease, the emergency response could potentially have a great impact on the US food system. The need to prevent disruptions in business continuity prompted the development of the proactive risk assessment approach, which would help inform decisions makers prior to and during an FAD incursion in the US livestock industry. Risk assessment is one of the four steps in the process of risk analysis following the OIE framework. The other components include the hazard identification, risk management and risk communication. Hazard identification focuses on providing an understanding of the biology and epidemiology of the agents of concern. Risk assessment is focused on determination of the probability of entry, establishment and spread of a disease, in conjunction with the associated potential of biological, economic and public health ramifications (4). Risk is defined as a product of the likelihood of occurrence of the event and the magnitude of the consequences. Risk assessment is broken down to two main components, release and exposure assessment. The release assessment seeks to identify the potential pathways for disease introduction (6). The exposure assessment determines the potential pathways leading to exposure of susceptible animals. In the event of a foot-and-mouth disease (FMD) outbreak in the U.S. livestock industries, local, State, and Federal authorities will implement a foreign animal disease emergency response. This
response consists of a control and eradication strategy that will utilize quarantine and movement control measures to prevent further spread of FMD virus. The authorities will issue official permits to allow movement of susceptible animals, and their products, from premises identified in a quarantine order during an outbreak. A request for a movement permit must be supported by a risk assessment (or some scientifically-based logical argument) to demonstrate that the risk associated with the movement of the product in question is acceptable (3).

The concept of proactive risk assessment (PRA) is based on traditional risk assessment tenets. It is a new process which was developed to support the recognition by government and industry for the need to allow business continuity planning prior to a disease outbreak. The risk assessment is done in advance of the outbreak in order to minimize disruptions to industry and consumer markets. The evaluation addressed the current industry practices, such as the just in time product delivery systems. It also identifies potential areas of risk, which can further be reduced by mitigation procedures (3). The goal of the process is to identify the most worrisome commodity and pathogen combinations, evaluate the associated risk, and develop mitigation strategies that are acceptable to all stake holders.

**Methods**

This PRA was developed as a public-private partnership between government, academic and industry stakeholders including USDA Center for Epidemiology and Animal Health and USDA VS Center for Animal Health and Emergency Management, University of Minnesota Center for Animal Health and Food Safety, industry stakeholders and other subject matter experts. The process follows the OIE risk analysis guidance and uses both qualitative and quantitative methods as applicable.

This PRA focused on the risk associated with the movement of FMD infected, but undetected pigs to a slaughter facility and the processing of these animals into RTE products, during an FMD outbreak. The estimation of this risk involved the evaluation of multiple pathways — from the introduction of a virus or a latently infected pig on-farm through the slaughtering and processing of the pig into RTE product. The likelihoods of virus moving successfully from farm to processing plant were evaluated using varying levels of surveillance. The assessment took into consideration all applicable regulations, including preventive measures already in place, as well as additional preventive measures that will be implemented during an outbreak.

The assessment evaluated the risk that Ready-to-Eat (RTE) pork could be contaminated with FMD virus from potentially infected but undetected pigs, shipped to a FSIS inspected slaughter facility during an FMD outbreak. It involved (1) Determination of the likelihood that animals from which the product was derived were infected with FMD at the time of slaughter and (2) the likelihood of FMD surviving RTE product preparation steps. A SLIR (susceptible, latent, infectious, and recovered) disease model for on-farm spread of disease was built, based on the Reed Frost epidemic disease spread model. Figure 1 shows the differential equations and input values used in modelling the disease stages. The results from the SLIR model were used to simulate the number of animals that could be shipped to slaughter using different surveillance protocols. Estimation of the risk of infected, but undetected pigs not being detected at the slaughter facility and subsequently processed into RTE product was performed using a qualitative approach.

1 During an outbreak, APHIS conducts numerous product-specific risk assessments taking into consideration all permit requirements and preventive measures currently in place.

2 Normal day-to-day operations and preventive measures are in place via FMD Response and Preparedness plans, HACCP plans, Good Manufacturing Practices (GMP), State regulations and Federal regulations as required by FSIS, FDA, and APHIS

**Results**

The results indicated that regardless of the surveillance strategy used, it was likely that a small number of infected, but undetected animals will be processed into finished RTE products. The number of pigs will be small, but the range of pigs that could be processed can be quite large if multiple farms are infected, but undetected. For an infected farm of 1,000 pigs, assuming no movement of newly susceptible pigs onto the farm during the 30 day period, the results of the SLIR model indicated that it would take a minimum of 3.12 days after an introduction of virus (or latently infected pig) to observe the first clinically infected pig with a 95% detection probability, when the surveillance method was based on testing 30 randomly selected pigs with rRT-PCR. At this time, there are already 262 infected pigs in the herd (168 latent, 62 pre-clinical and 32 clinically infected pigs). All susceptible pigs would be infected by 5.5 days after the introduction of virus.
The probability of receiving at least one or more infected, but undetected pigs at a processing facility ranges is greater than 85%, but the specific number received depends on the surveillance method employed. This percentage is based on shipping pigs from one farm and up to 20 farms that contain 1,000 pigs/farm. On average, the number of infected/viremic pigs that will be shipped is small, but the issue is that the range of pigs that could be infected or viremic and not detected can be quite large.

Data gaps
An important output from the PRA process is the determination of areas of uncertainty (data gaps) that need to be addressed in order to more fully evaluate the risks during an outbreak. This helps prioritize research activities to obtain answers to these areas of data paucity before the occurrence of an outbreak.

Discussion
A number of worldwide FMD responses have resulted in undesirable impacts to the business and livestock industry they seek to protect. Development of such proactive risk assessments prior to an FMD outbreak provide a novel approach towards achieving adequate movement control and bio-security without compromising business continuity. This process serves as a great example of how public-private partnerships that involve industry, academia and government can work together to achieve better preparedness and develop effective response plans that address the needs of disease control and eradication as well as continuity of business needs during an FMD incursion or any animal health emergency in the United States.

Figure 1: Schematic model of disease stages in a farm.

Legend:
- Susceptible (S) = animal susceptible to infection.
- Latent (I) = pigs have been exposed, but have not shed virus or developed clinical signs.
- Pre-clinically infected (I) = viremic, but have not developed clinical signs.
- Clinical (I) = animal is currently infected and showing clinical signs of disease.
- Recovered (R) = Animal has recovered from disease.
- $B$, $\lambda$, $\alpha$, $\mu$ = transmission coefficients for transitions from one stage to the next stage.

References:
2. GAO, High containment biosafety laboratories; DHS lacks evidence to conclude that Foot and Mouth Disease Research can be done safely on the US mainland, GAO-08-821T (Washington, D.C.: May 22nd, 2008).
Determine the room for improvement of processes within the management of crisis and their prevention – the maturity model

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Abstract
Crisis within the meat sector usually causes high economic losses for the affected sector and frequently for other sectors, too. Interrupted or poor communication channels are weak points in management-systems, especially in the management of crisis situations or of the prevention of crisis. In a consequence necessary information for a proper decision making is missing or not available in time. Therefore, processes that provide a sufficient and fast exchange of information between all private and public actors play a crucial role. Against this background the idea of the Engage-Exchange-Model (EEM) was developed to optimize and provide processes to exchange different information between public and private organizations in crises and regular operations. Further on specific information were defined that are necessary to support processes to prevent crisis or to support the crises management. To assess existing or new processes which support an EEM, the maturity model (ISO/IEC 15504) was successfully applied. Even if it was developed for the IT-sector, it also could be used within the meat sector by adapting its main inputs towards the specific requirements. The main advantages of the maturity model are the categorizations of the processes in capabilities-levels. This leads to an absolute assessment of the single processes on a given scale from 0 to 5 instead of a relative assessment in comparison to other methods, like benchmarking or auditing. This will support the decision-making whether to improve a process or not. In this study the inner and inter-organizational processes of public and private actors within the meat sector are investigated. Missing or poor processes in order to prevent crisis or to support the crisis management could be identified and build the basis to determine a specific EEM for the investigated meat sector as a public-private partnership.