APC

WATCH THEM *thrive*

PLASMA BIOSAFETY

A CONVERSATION WITH JERRY FRANKL, PRESIDENT OF APC

BIOSAFETY

Jerry Frankl
President of APC

"Spray dried animal plasma is an effective, safe, high-quality ingredient that can be confidently used in animal feeding programs. Each step of the process is carefully monitored to maintain product integrity and traceability. Our team is dedicated to the safety of our products throughout the entire production process."

—Jerry Frankl

How does APC mitigate the risk of foreign animal diseases?

Manufacturing safe and effective products is our number one priority. As the global leader in spray-dried animal proteins, we make continuous investments in the latest technologies – sometimes exclusive to us – to ensure we are providing a safe product 100% of the time. We invest significant resources into conducting scientific trials that validate our manufacturing practices inactivate global diseases of concern. The manufacturing process of spray-dried plasma follows the World Health Organization guidelines for the production of human transfusable blood products. In fact, extensive research validates APC's spray-drying and post-drying heat treatment processes inactivate more than 99.99%* of tested viruses.

Virus	Envelope	Genome	Surrogate Virus	Virus Inactivation Steps		
				SD	Storage 20C for 20 min (Warm Box)	Combined SD + WB
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)	Yes	(+)ssRNA		2.1 - >4.0	>4.0	6.1 – 8.0
Porcine Epidemic Diarrhea Virus (PEDV)	Yes	(+)ssRNA		>5.15	2.7- >3.5	>7.85 - 8.65
Classical Swine Fever Virus (CSFV)	Yes	(+)ssRNA	BVDV	>5.0		>5.0
Swine Influenza Virus (SIV)	Yes	(-)ssRNA		2.8	1.9	>4.7
Pseudorabies Virus (PRV)	Yes	ssDNA		>5.30		>5.3
African Swine Fever Virus (ASFV)	Yes	dsDNA	PRV	~4.0	In testing	~4.0
Senecavirus A (SVA)	No	(+)ssRNA		6.7	4.9	11.2
Swine Vesicular Disease Virus (SVDV)	No	(+)ssRNA		>6.00	4.9	10.9
Porcine Parvovirus (PPV)	No	ssDNA		2.6*	3.1*	>5.7

**99.99% is equivalent to a 4 Log reduction*

"We invest significant resources into conducting scientific trials that validate our manufacturing practices inactivate global diseases of concern."

How can you assure there is no risk of disease transmission when using plasma?

Because our process of spray-drying to 80° C throughout substance is recognized to inactivate 99.99% of most viruses. This is recognized as a 4 Log reduction. This standard is globally accepted by scientists and governments and is specifically supported by European Directive 2002/99/EC; Annex III. This is a key step in the Good Manufacturing Practices we employ at all APC plants. In addition, our research has shown that naturally occurring neutralizing antibodies against various viruses in plasma also have significant inactivation capacity. We also employ post-drying heat treatment which also provides a significant Log reduction of certain viruses.

What does APC do to ensure the spray-drying kill step is effective?

APC utilizes computer-controlled processing for spray-drying plasma, monitoring the process, assuring a minimum processing temperature of 80° C throughout substance is achieved. APC has also conducted extensive trials that validate this process, which are available in peer-reviewed, published journals.

What happens to the plasma if there is a breakdown in the spray-drying process?

The fact is spray-drying is a very consistent and reliable process that occurs exactly as it should the vast majority of the time. On the rare occasion when our systems and operators find that spray-drying has not reached 80° C throughout substance, alerts built into our processing systems initiate special procedures for the affected product. The product is then moved to a quarantine area and held until further disposition can occur. Quality and Manufacturing personnel review the event and conduct further product testing.

What is the potential of cross contamination of plasma?

The risk is very low within our manufacturing process. Plasma manufacturing is a closed system from the time of collection to the output of the product at packaging. We have strict biosecurity procedures for all incoming and outgoing truck traffic and visitors. The tankers used to transport liquid blood are owned by APC or exclusively dedicated to APC. Each tanker is Cleaned In Place before loading and after unloading. Our plants operate in a closed system and use all stainless steel equipment with extensive sanitation procedures. Visitor and truck traffic protocols are in place and enforced. Employees are dedicated to wet and dry side duties and we utilize sanitary barriers throughout our facilities. APC always uses new packaging, and we employ a post-drying heat treatment process that includes significant hold times. We do everything within our control to manufacture a safe product.

All APC products are packaged primarily in bags or totes and are then double-wrapped prior to shipment.

All feed ingredient/additive suppliers are working with customers to minimize risk of cross contamination once it leaves their facilities.

It's important that all parties in the process have effective biosecurity procedures in place and stay vigilant.

"Transportation and storage at facilities where spray-dried plasma may be held with other ingredients is a concern – just as it is for other ingredient manufacturers. It's important that all parties in the process have effective biosecurity procedures in place and stay vigilant."

What other technologies does APC employ?

The manufacturing process for the production of spray-dried animal plasma follows the World Health Organization guidelines for the production of human transfusable plasma products. We use manufacturing steps including processing from healthy animals and multiple, robust virus inactivation and removal procedures including spray-drying, post-drying heat treatment and in some facilities, UV-c irradiation.

Key Biosafety Steps

1. **Donor Selection:** Blood is collected at officially inspected abattoirs from animals that have been examined and passed as fit for slaughter for human consumption.
2. **Testing of Plasma:** All lots of plasma are tested post-production, prior to finished product release.
3. **Viral Inactivation & Removal Procedures:** Spray-drying to minimum 80° C throughout substance, computer controlled with continuous monitoring and for porcine products, Post-drying Heat Treatment at a minimum 20° C for 14 days.

World Health Organization

"The manufacturing process for the production of spray-dried animal plasma follows the World Health Organization guidelines for the production of human transfusable plasma products."

Recent research affirms use of plasma in feed is safe

WHAT ABOUT RECENT STUDIES THAT PROPOSE THE INFECTIOUS DOSE OF ASFV IN FEED INGREDIENTS IS RELATIVELY LOW?

Two recent studies were conducted feeding ASFV infected, unprocessed liquid porcine plasma mixed in feed to pigs at IRTA-CReSA Animal Health Research Center in Spain. Pigs were fed a minimum infectious dose that was higher than previously reported for 14 consecutive days in feed. No pigs showed ASFV symptoms nor was infection detected in various tissues in those 14 days, or thereafter. The study was repeated with a separate group of pigs fed an even higher dose of ASFV in the feed and again, pigs remained healthy during the 14 day feeding period and beyond. The current information suggests the amount of ASFV contamination in feed needed to infect pigs is relatively high. Feed and feed ingredient suppliers using good manufacturing practices with high biosecurity standards should represent a very low risk of ASFV spread by contaminated feed or feed ingredients.

Blazquez E, J Pujols, J Segales, F Rodriguez, C Rodriguez, J Rodenas, J Polo. 2020. Commercial feed containing porcine plasma spiked with African Swine Fever Virus is not infective in pigs when administered for 14 consecutive days.

WHAT ABOUT THE ASSERTION BY CFIA THAT SPRAY-DRIED PLASMA WAS TO BLAME FOR PEDV OUTBREAKS?

Looking back, the industry now recognizes there are many risk factors associated with the transmission of PEDV beyond feed ingredients. Two very important aspects that affect PEDV transmission were not included in their epidemiological report, including truck traffic and animal movement through known PEDV contaminated sites. Hindsight is 20/20 and a published paper in the journal *Transboundary and Emerging Diseases* shows spray-dried plasma was the least likely variable to have caused the outbreak.

Russell LE, J Polo, D Meeker. 2020. The Canadian 2014 porcine epidemic diarrhea virus outbreak: Important risk factors that were not considered in the epidemiological investigation could change the conclusions. Transboundary and Emerging Disease. 2020;00:1-12. doi: 10.1111/tbed.13496

The OIE Scientific Commission on Animal Disease recognize the safety of SDPP as long as good manufacturing practices are followed.

OIE

Why should we consider using plasma?

Spray-dried plasma is an essential health management tool for the swine industry. Thirty years of research shows that using spray-dried plasma in pig feed reduces mortality by 50%, increases gain by 30% and improves feed intake by 25%. We hear from swine producers that they can't afford to give up plasma. After a PEDV break in Western Canada, one producer told us he is going back to using plasma. He's losing $5 per pig without plasma in the diet. Using spray-dried plasma reduces labor and makes starting pigs easier.

How safe is plasma vs other feed ingredients?

Plasma is actually one of the safest ingredients you can use in diets. It's one of the most researched feed ingredients available today. There are more than 500 published journal articles that document both the effectiveness and the safety of the product. The real risk is what happens to the pigs when you don't use spray-dried plasma.

Can other feed ingredients replace plasma?

No other product can replace the functionality of plasma. We make this statement based on over 35 years of research trialing plasma against many other proposed "plasma replacers". None of them have ever been able to match plasma's consistent performance.

Do animal proteins pose a bigger risk than vegetable proteins?

No. There is no additional risk when using animal proteins that follow Good Manufacturing Practices. The risk of post-processing contamination is the same for any feed ingredient whether animal or vegetable.

What is APC's plan to supply the market going forward?

APC, as part of the global spray-dried plasma industry, is seeking input from independent experts from various disciplines to review and validate processing procedures and validate previous scientific work.

FOR MORE INFORMATION, visit APCproteins.com

REDUCES MORTALITY BY 50%

INCREASES GAIN BY 30%

IMPROVES FEED INTAKE BY 25%

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