



PLASMA BIOSAFETY

A conversation with Dr. Louis Russell, President and CEO of APC

APC is the largest supplier of plasma in the world. Do you produce any plasma in China?

Yes, APC operates 20 plasma manufacturing facilities globally, including four plants in China.

Considering ASF is endemic in China at this time, how are you handling the plasma you produce there?

We are handling plasma produced in China with the same proven Good Manufacturing Practices we use at all of our facilities. In addition, all plasma that APC manufactures in China undergoes an additional step after drying, processed at 60°C for 20 minutes, which is a proven viral inactivation step. The plasma APC produces in China is sold only in the local market and is not exported to any other country. From a regulatory perspective in China, porcine plasma is currently allowed to be fed to swine. Realistically, there is limited usage in the swine industry there today. Most of our locally produced product is sold for aquaculture and poultry applications.

Can ASF be found in blood?

Yes, in liquid form. The World Organisation for Animal Health (OIE) indicates ASF can be found in all body fluids and tissues of infected pigs.

Who is testing for ASF in China?

Many segments of the Chinese swine industry are currently testing for ASF as required.

What about other regions of the world that have periodic outbreaks of ASF, such as Poland?

APC only collects blood from meat packing facilities that are located in ASF free countries or zones. Animals have been federally inspected and deemed healthy and fit for slaughter for human consumption. Therefore, there is no risk of plasma containing ASF in these regions.



*Dr. Louis E. Russell
President & CEO of APC*

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Can ASF be transmitted through porcine plasma?

Liquid plasma would pose a risk in the raw form. However, APC produces spray-dried plasma following Good Manufacturing Practices that have been validated to inactivate recognized pathogens, including ASF. There is no risk of infective ASF in APC's spray-dried plasma.

What about porcine plasma manufactured in other APC plants?

With the exception of our China plants, all other APC plants are manufacturing in countries or zones free of ASF. This status is confirmed by government officials and again at the time Health Certificates are signed for export.

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 proven to inactivate 99.99% of tested viruses. This is a greater than 4 Log reduction, and 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, we employ post-drying heat treatment which provides a greater than 7 Log reduction in various tested 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. 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?

On the rare occasion when our systems and operators find that spray-drying has not reached 80° C throughout substance, the system is shut down and any affected product is moved to a quarantine area and held until further disposition can occur. Quality and Manufacturing personnel review the event and conduct further product testing. We are then able to direct the product for use in other species where foreign animal diseases are not a concern, such as in pet food, poultry, ruminant or aquaculture diets.

What is the potential of plasma being contaminated during manufacturing?

The risk is very low within our manufacturing process. We own the process from start to finish – from collection site installation to transportation to manufacturing and storing the finished product. Our plants operate a closed system and use all stainless steel equipment with extensive sanitation procedures. We have sought third party input to ensure our processing and biosafety procedures are stringent. APC continues to invest in improvements and the latest technology. We have a high level of confidence in our manufacturing because we continuously validate our processes and procedures to ensure a safe product.

Where do the risks for product contamination lie?

Once the product leaves our warehouse, we do relinquish control and the level of risk varies as there may be many stopping points for products. 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.



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What about other foreign animal diseases?

APC takes the risk of foreign animal diseases seriously. We invest significant resources into conducting scientific trials that validate our manufacturing practices inactivate global diseases of concern, including PEDv, PRRS, SVD, ASF and others. Results of these trials are published and show consistent inactivation.

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 donors / animals and multiple, robust virus inactivation and removal procedures including spray-drying, post-drying heat treatment and in some facilities, UV-c irradiation.



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**World Health
Organization**

Can APC guarantee plasma is ASF Free?

Yes. Certified ASF Free plasma is available today from any APC manufacturing facility located in an ASF free country or zone. APC guarantees our customers a certification that our spray-dried plasma will not cause infection.

What is Certified ASF Free Plasma?

Certified ASF Free Plasma is manufactured in a region free from ASF, using our validated Good Manufacturing Practices and is based upon governments signing Health Certificates which certify there is no disease present in the exporting country or zone.

What is the safety record of feeding plasma to swine, globally?

In the more than 35 years that spray-dried plasma has been fed to pigs, there has never been a confirmed case of plasma being the cause of a disease. The product is fed to millions of pigs every year – if spray-dried plasma was a problem, you would know it.



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

What about the assertion by CFIA that spray-dried plasma was to blame for PEDv outbreaks?

The statement made by Canadian Food Inspection Agency (CFIA) in 2014 was not a complete representation of the situation. Two very important aspects that affect PEDV transmission were not included in their epidemiological report, including truck traffic and people movement. Hindsight is 20/20 and a review paper of the Canadian PEDv outbreaks has been submitted for publication and will soon be presented that shows spray-dried plasma was the least likely variable to have caused the outbreak.

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 piglet diets 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 been able to match plasma's consistent performance.

Do animal proteins pose a bigger risk than vegetable proteins?

No. When Good Manufacturing Practices are used in producing animal protein products, there is no risk from the finished product, post-manufacturing. The risk for animal protein based products is in post-production scenarios, such as transportation and people movement. It's important to have mitigation procedures in place for any ingredient, whether it is animal or vegetable protein.

**REDUCES
MORTALITY
BY 50%**

**INCREASES
GAIN 
BY 30%**

**IMPROVES
FEED INTAKE
BY 25%**



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

APC, as part of the global spray-dried plasma industry, is in the process of establishing an independent board of experts from various disciplines to review and validate processing procedures and validate previous scientific work. We expect them to provide guidance to spray-drying manufacturers and transparency to the industries we serve.

For more information, visit
www.functionalproteins.com