Current and Potential Pathways for Regulatory Approval of PRP in China

What is PRRS?

The PRRS virus has ravaged the global pork industry for more than three decades.

Porcine Reproductive and Respiratory Syndrome (PRRS) is a dynamic, often fatal virus that affects millions of pigs around the world. It causes suffering and prematurely kills millions of pigs each year.

PRRS has become increasingly endemic and unseasonal. It impacts millions of producers – of all sizes and scales – around the world.

At any given time, greater than 60% of sow herds are PRRS positive in the U.S.

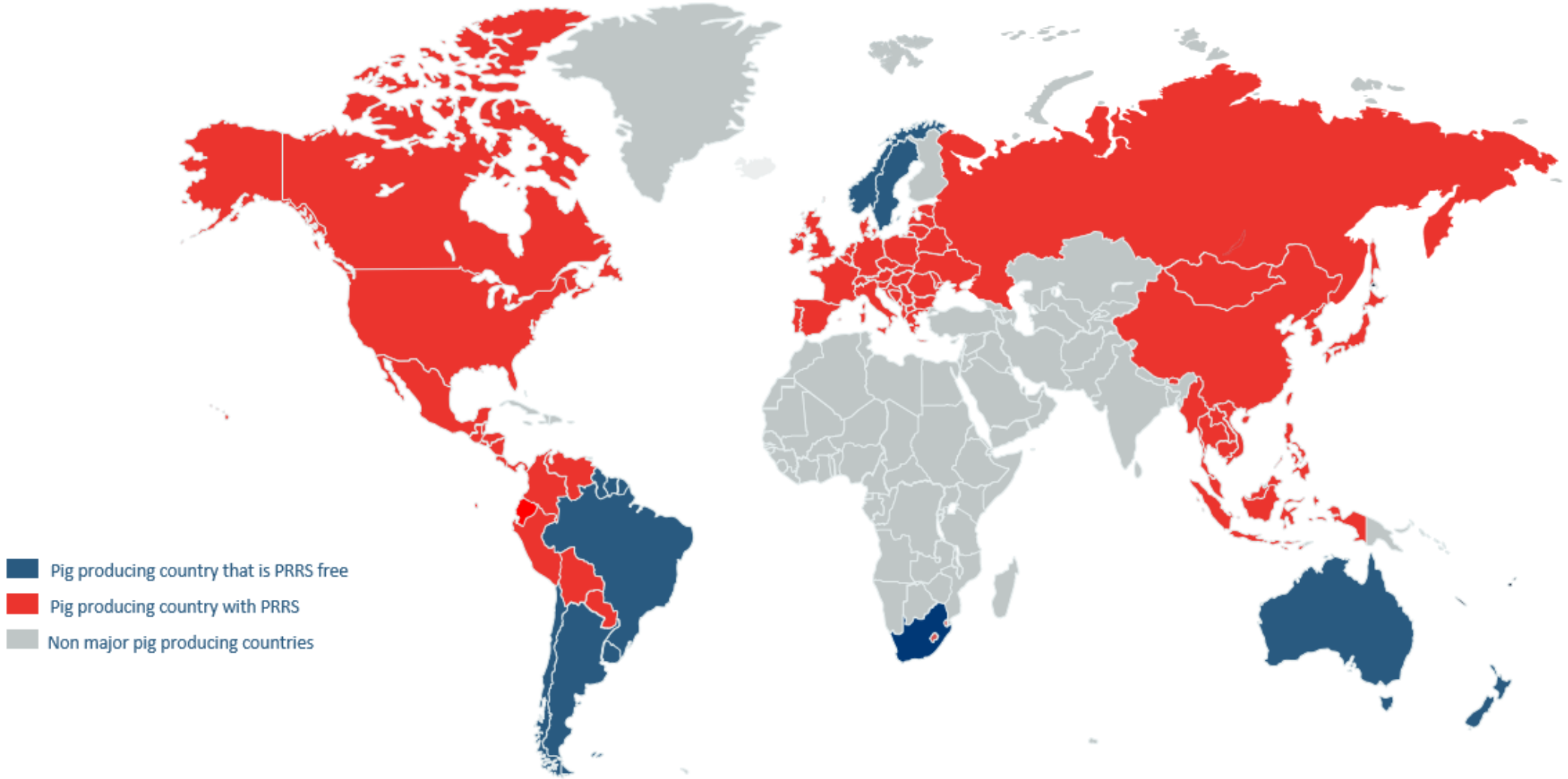
Current vaccines only reduce symptom severity, and the antibiotics used to treat an infected pig's weakened immune system can exacerbate the development of other resistant bacterial diseases.

The PRRS virus costs the pork industry **more than $664 million per year**, according to a study from Iowa State University.[1]

1. Holtkamp et al (2013), Trevisan et al (2013), https://www.thepigsite.com/news/2010/11/prrs-costs-canadian-swine-industry-130m-per-year-1

PRRS is a global problem for pork producers

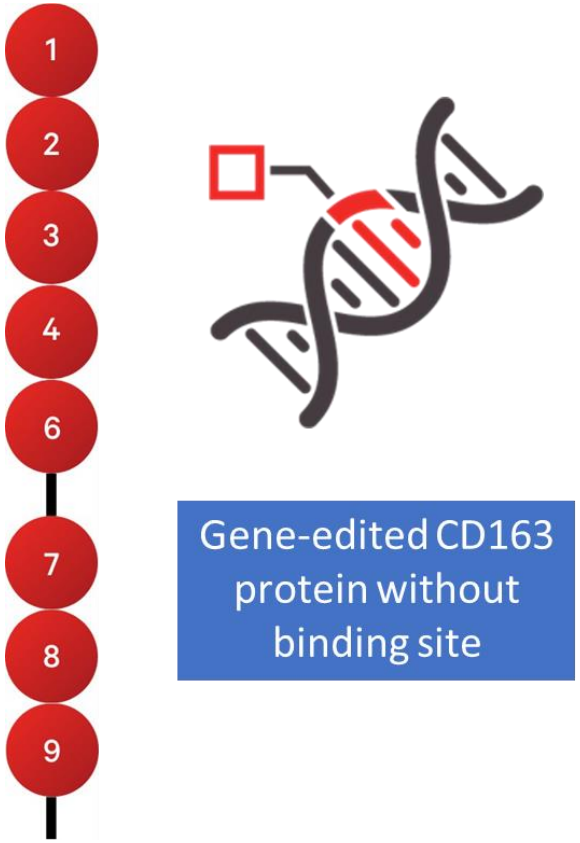
Endemic in most major pork producing countries



- Source: PIC® estimates

PRRS Resistant Pig (PRP) builds upon the latest scientific achievements

- Partnership with researchers at the University of Missouri to identify a solution.
- Gene editing technology used to **remove** the binding site of the target protein (CD163).
- The PRRS virus cannot bind to the gene edited CD163 protein, making the pig resistant to the disease.
- Like humans inherit traits from their parents, the pig's offspring will inherit the PRRS-resistant trait.



Strict regulatory process for GMO in China

Regulatory approval department： MARA

Safety evaluation guideline

- Three types: animals, plants, microorganisms
- Five phases evaluation
- Two ways: notification and approval

Technology supporting system

1. National Agriculture Biosafety Committee(NBC)
2. National Agricultural Biosafety Standardization Technical Committee
3. GMO Biological Technology Detection Centers

Approval process and population size requirements for GM animals

MARA assigned validation studies

Requirements of population size (pigs)

Intermediate Test	Enviornmental Release	Production Test
The size (upper limit) of each test site was 20 ~ 40.	The size (upper limit) of each test site was 500.	The size (upper limit) of each test site was 10,000 .

Safety Evaluation data requirements for GM animals

- Molecular characterization (expression vectors, integration of target genes)
- Genetic stability (two successive generations)
- Health status (behavior, appearance, physiological indicators)
- Trait efficacy evaluation (effectiveness data of target traits, performance data)
- Environmental adaptability (ability to survive, grow, reproduce, etc)
- Escape (release) of the GM animals and impact on the environment
- Food safety (toxicological and sensitizationevaluation, components, nutrition evaluation, etc)

The Chinese government has shown a positive attitude towards GE breeding

1. The keynote clearly supports biological breeding research and development and industrialization

2. Pay attention to international regulatory developments and promote the progress of regulatory rules

3. The industrialization supervision of GE has been gradually opened up, and the lanch of GE breeds has been accelerated

2020 GE breeding into the fast lane

2020/02

MARA

"Key Points of Promoting the Development of Modern Seed Industry in 2020", to accelerate the application of new technologies in biological breeding

2022/01

MARA

- Revision of the Administrative Measures for the Safety Evaluation of Agricultural GMO;
- The "Guidelines for the Safety Evaluation of GE Plants for Agricultural Use" was released

2022/06

IPO review of the Science and Technology Innovation Board

A new science and technology industry sector will be added to encourage the listing of biological agriculture and biological breeding enterprises

2023/04

MARA

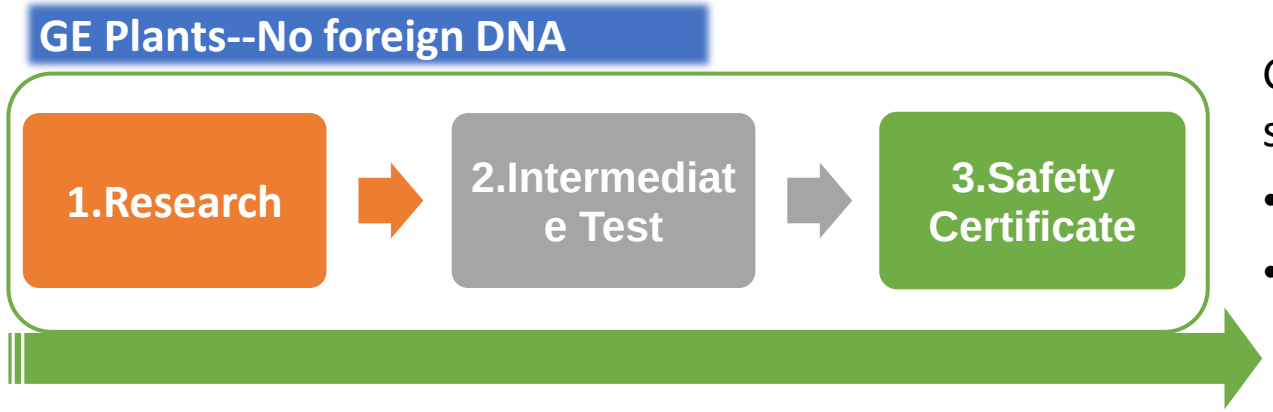
The first GE plant safety certificate product, high oleic soybean, was approved

2024/05

MARA

The first GE staple food product was approved for safety certificate (powdery mildew resistant high-yield wheat, yield trait improved corn)

GE animals safety evaluation is expected to be simplified

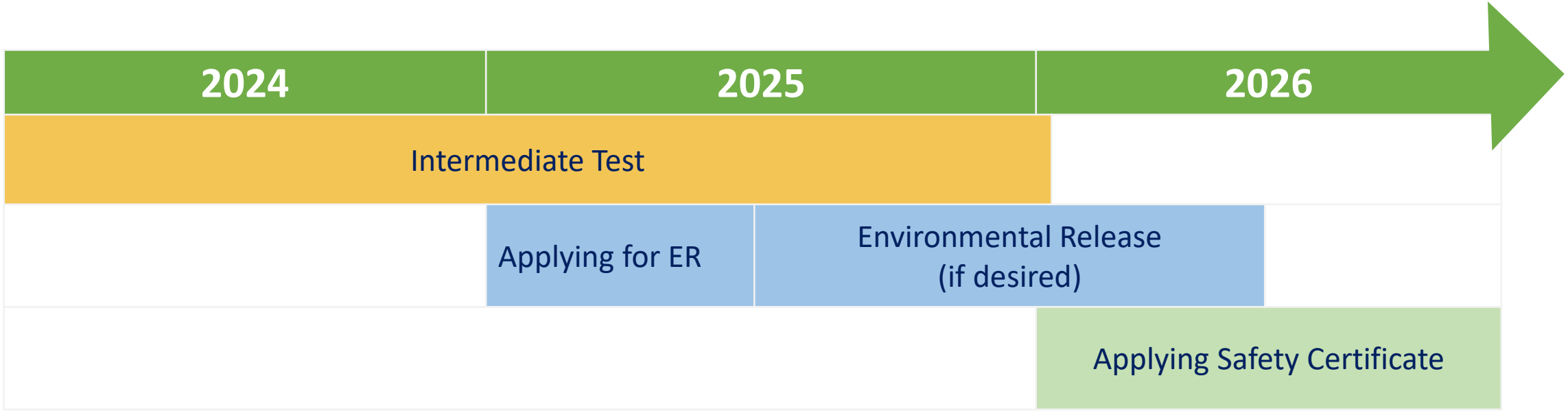


Guidelines for GE plants were issued in 2022, and several products have now been approved

- Two stages are simplified
- Shortened time

The guidelines for GE animal are expected to be similar to the plant guidelines...

Outlook of PRP regulatory approval in China



Thanks!