MSD Animal Health

Porcilis® Lawsonia ID

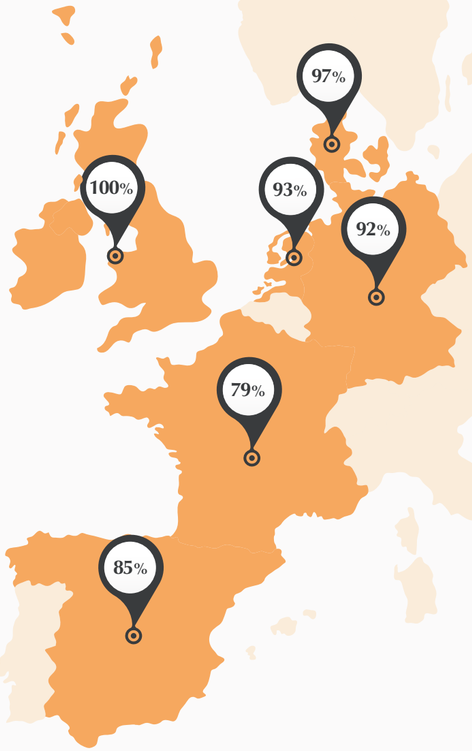
THE IDAL WAY

• Needle-free • Efficacy • Innovation •

Prevalence of ileitis[1]

Between 80-100% of European farms are infected with *Lawsonia intracellularis*

Herd prevalence



Herd prevalence = % of herds with at least one animal with antibodies against Lawsonia intracellularis, as Mirjam Arnold published in 2019 at the Porcine Health Management magazine.

Risk factors associated with the direct detection of *L. intracellularis* in pigs[2]

Created based on the biological plausibility and distribution of 12 studied variables in:

3 CATEGORIES

- Environment
- Internal Biosecurity
- Animal related

CONCLUSIONS

Particular importance in disease prevention:

Weaning and subsequent post-weaning environment of nursery pigs.

Positive influence in disease prevention:

- **Low number** of NP per pen.
- More than **78% of slatted** floor in nursery.
- ZnO — The absence of **zinc oxide.**
- Maximum weaning weight of **7.8 kg**

Attempts to control *L. intracellularis* in pigs by minimizing the various risk factors associated on farm, is extremely complex and not very effective. A more profitable and productive way to reduce *L. intracellularis* infection is to individually vaccinate pigs.

Economic impact of ileitis*

The major source of economic losses associated with ileitis arise from productivity drops caused by the disease.

Increase in growth differences → uneven batches → greater costs.

AVERAGE DAILY WEIGHT GAIN

Can decrease by up to 38%

Increase in the time to reach slaughter weight.

FEED CONVERSION RATIO

Can increase by up to 27%

Lower increase in weight **with the same consumption of feed.**

MORTALITY

Can increase by up to 70%

In the acute stage of the disease (pigs by the end of the fattening stage).

The subclinical ileitis has a 20.8% impact on ADWG and 20.4% impact on Feed Efficiency over 6 weeks.[3]

*Based on internal information, provided by Derald J. Holtkamp

Economic value of the estimated losses in the fattening stage.

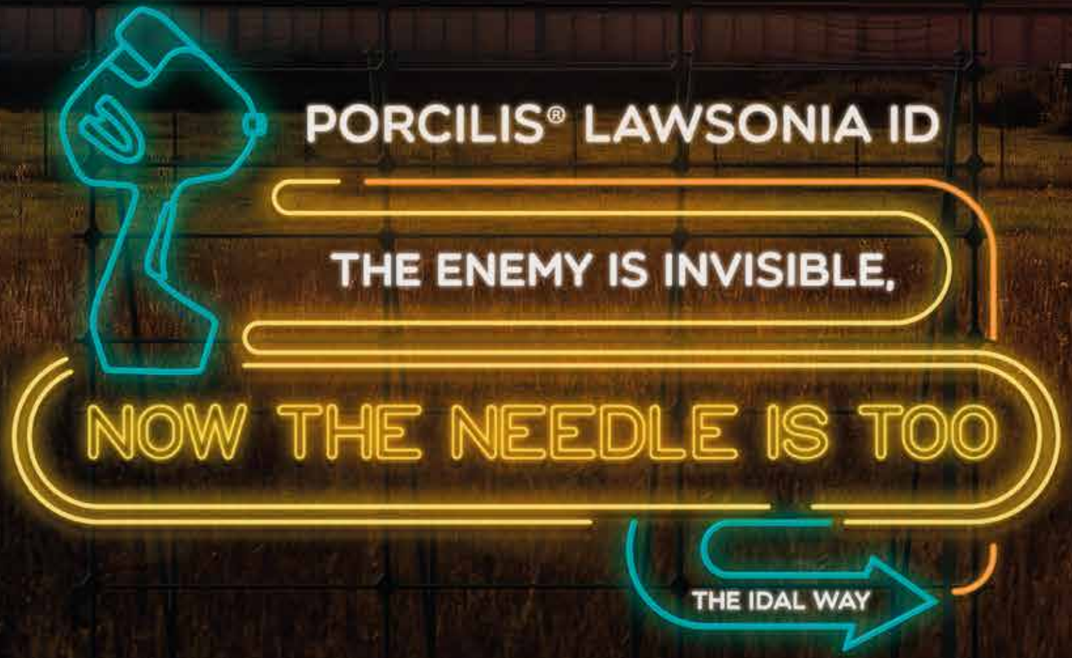
01 In Europe, the cost of **1-5€ per pig** has been estimated.

02 During the fattening period in continents like Australia, with a production similar to Europe's, losses already reached **$25 per sow** per year (Cutler & Gardner, 1988).

03 In the United Kingdom, they calculated a **loss of £2 to £4 million** per year due to ileitis (McOrist et al, 1997).

04 A 2018 report* from Prof. Derald Holtkamp, Iowa State University, estimates the loss due to ileitis at the end of the fattening period as **between $5.98 and $16.94 per pig marketed**

VACCINATING IS THE SOLUTION



TAKING CARE OF ANIMAL WELFARE:
LESS STRESS, NO PAIN AND NO INJURIES AT POI*.

SAFER AND EASY HANDLING.
NO NEEDLES MEANS FEWER RISKS:

- FOR YOU (NO SELF-INJECTION).
- FOR YOUR PIGS (LESS IATROGENIC TRANSMISSION).
- FOR THE CONSUMER (NO BROKEN NEEDLES IN THE CARCASS).

THE WISEST DECISION:
INTRADERMAL VACCINATION IS THE MOST INNOVATIVE AND EASY WAY TO CONTROL ILEITIS.

*Point of inyection

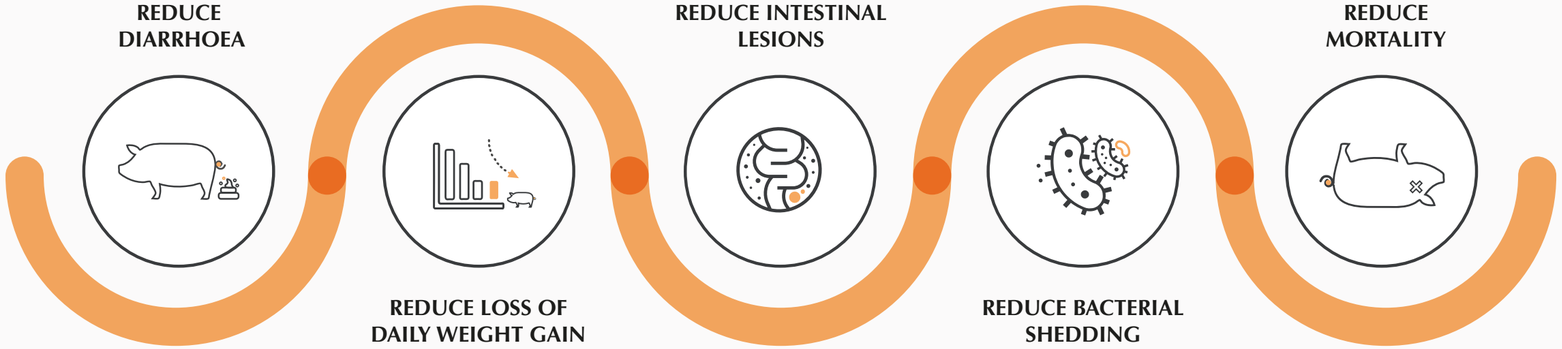
Porcilis® Lawsonia ID

- **Ready to use** in a single step.
- There is no need to use water.
- It guarantees that **each** animal receives the **exact dose** (0.2 ml).

- **Intradermal administration** with IDAL device.
- **No interference** with feed, water chlorination, antibiotics, etc.

- **May reduce the use of antibiotics.**
- It can be reconstituted with **Porcilis PCV ID.**

Proven clinical effects of vaccination with **Porcilis® Lawsonia ID[4]**



Efficacy of a novel intradermal *Lawsonia intracellularis* vaccine in pigs against experimental infection and under field conditions.[5]

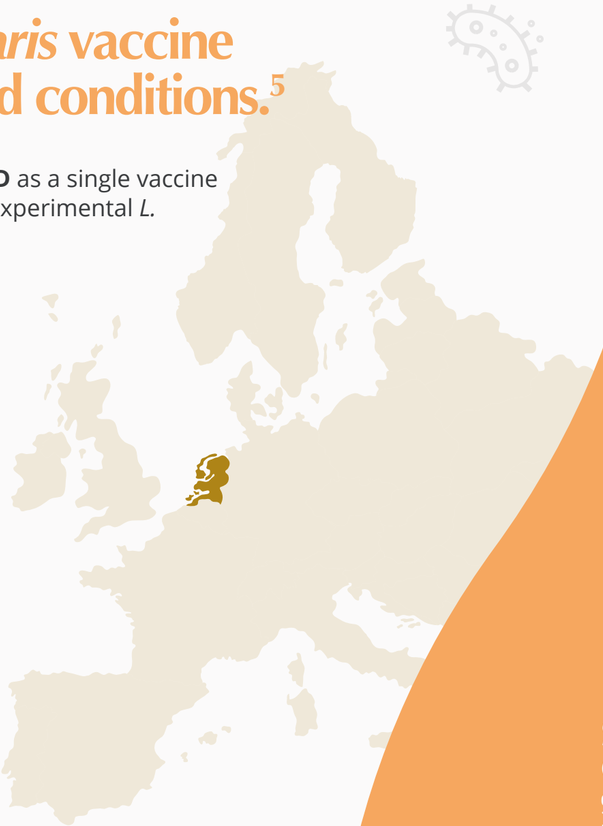
The results of the two experimental vaccination-challenge studies showed that **Porcilis® Lawsonia ID** as a single vaccine or in associated mixed use with **Porcilis® PCV ID,** induced statistically significant protection against experimental *L. intracellularis* infection, **4 weeks** or **21 weeks** after vaccination.

Country:
the Netherlands

Design:
2 negative controlled, randomised and masked studies.

Farm:
commercial pig herd with a history of PPE associated mortality (acute ileitis close to slaughter age).

Total number of animals:
3261 pigs > piglets randomly allotted to groups of 25 piglets each.



Study 1

25 piglets

Vaccinated with **Porcilis® Lawsonia ID** at 3 weeks of age.

25 piglets

Vaccinated **once orally with live vaccine** at 3 weeks of age.

25 piglets

Non-vaccinated (control)

Challenge: Oral administration of homogenized Li infected intestinal mucosa. **4 weeks after vaccination**

Study 2

25 piglets

Vaccinated with **Porcilis® Lawsonia ID mixed with Porcilis® PCV ID.**

25 piglets

Non-vaccinated (control)

Challenge: Oral administration of homogenized Li infected intestinal mucosa. **21 weeks after vaccination**

All pigs were euthanised and necropsied 21 days post-challenge.

Scoring system

(clinical signs of Li infection):

0 = normal
1 = mild diarrhoea (soft and shaped like peanut butter)
2 = moderate diarrhoea (loose like mush or yogurt)
3 = severe diarrhoea (watery and/or with incorporation of blood)

Other observation points

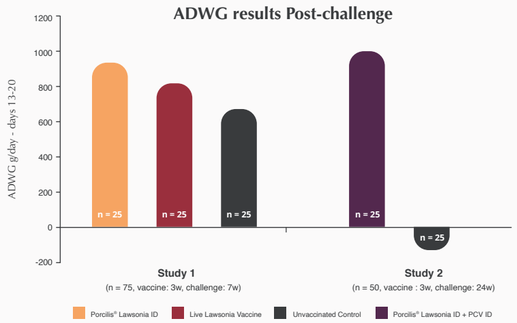
ADG, intestinal (ileum) lesions, serology (ELISA), DNA isolation (qPCR Li) from faeces and ileum mucosa, mortality rate.

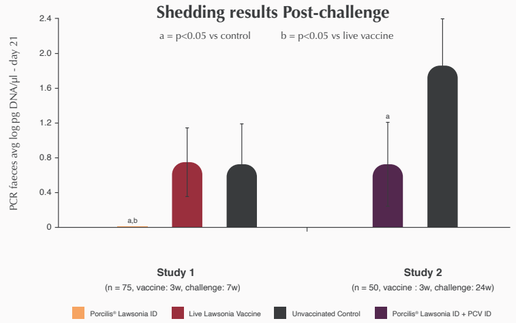
Results

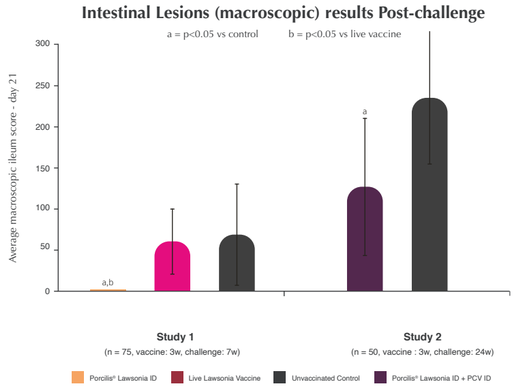
Table Post-challenge results ± SD of vaccination-challenge studies 1 and 2

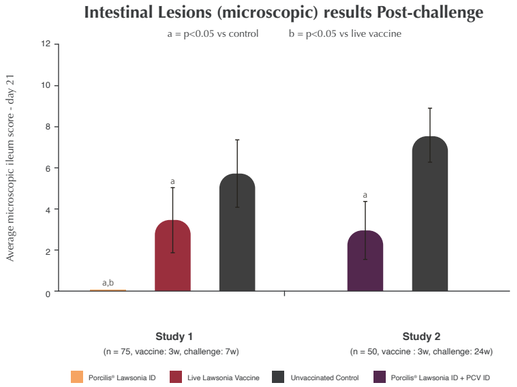
vaccine group	avg clinical score day 13-21	ADWG g/day day 13-20	PCR faeces avg log pg DNA/µl		PCR mucosa avg log pgDNA/µl day 21	avg macroscopic ileum score day 21	avg microscopic ileum score (IHC) day 21
			AUC	day 21			
Study 1: vaccination at 3 weeks of age, challenge at 7 weeks of age, necropsy 21 days after challenge							
Law ID[a]	0.3 ± 0.5	956 ± 119[d,e]	0.13 ± 44[d,e]	0.0 ± 0.0[d,e]	0.03 ± 0.04[d,e]	0.6 ± 1.5[d,e]	0.1 ± 0.3[d,e]
Live vaccine[b]	0.2 ± 0.4	812 ± 287	0.79 ± 0.91[d]	0.77 ± 0.81	0.50 ± 0.51	61 ± 81	3.4 ± 3.2[d]
Control	0.5 ± 1.0	674 ± 381	1.44 ± 1.13	0.73 ± 0.93	0 66 ± 0 60	68 ± 125	5.7 ± 3.3
Study 2: vaccination at 3 weeks of age, challenge at 24 weeks of age, necropsy 21 days after challenge							
Law ID + PCV ID[c]	1.3 ± 1.9[d]	1001 ± 710[d]	4.23 ± 1.51	0.71 ± 0.96[d]	0.19 ± 43[d]	129 ± 165[d]	2.9 ± 2.8[d]
Control	3.8 ± 5.4	-139 ± 1210	5.02 ± 1.65	1.90 ± 1.08	0.54 ± 61	241 ± 160	7.7 ± 2.6

[a] Porcilis® Lawsonia ID
[b] commercially available live attenuated Lawsonia vaccine
[c] associated mixed use of Porcilis® Lawsonia ID and Porcilis® PCV ID
[d] p<0.05 vs control
[e] p<0.05 vs live vaccine

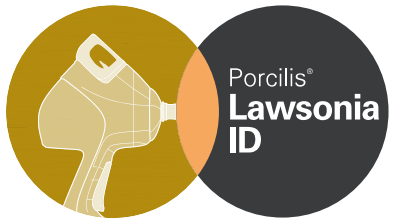








Porcilis® Lawsonia ID induces significant protection against experimental *L. intracellularis* infections.



THE IDAL® WAY

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[1] Arnold M. *et al.* Prevalence of *Lawsonia intracellularis* in pig herds in different European countries. Porcine Health Management (2019) 5:31. https://doi.org/10.1186/s40813-019-0137-6
[2] Arnold M *et al.* Correlation of *Lawsonia intracellularis* positivity in quantitative PCR and herd factors in European pig herds. Porcine Health Management (2021) 7:13 https://doi.org/10.1186/s40813-021-00192-4
[3] Armbruster G. *et al.* Evaluation of Tylan in a finishing pig subclinical ileitis challenge model. AASV. 2013. Pp. 237-242
[4] Technical data on Porcilis® Lawsonia ID (SPC). MSD
[5] Jacobs A.A.C. *et al.* Efficacy of a novel intradermal *Lawsonia intracellularis* vaccine in pigs against experimental infection and under field conditions. Porcine Health Management (2020) 6:25 https://doi.org/10.1186/s40813-020-00164-0

International summary of product information

Porcilis Lawsonia ID lyophilisate and solvent for emulsion for injection for pigs.

Indications for use:
For the active immunisation of pigs from 3 weeks of age to reduce diarrhoea, loss of daily weight gain, intestinal lesions, bacterial shedding and mortality caused by *Lawsonia intracellularis* infection.
Onset of immunity: 4 weeks after vaccination.
Duration of immunity: 21 weeks after vaccination.

Administration:
A single dose of 0.2 ml of reconstituted vaccine in pigs starting at 3 weeks of age.
Vaccinate pigs by the intradermal route using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a "jet-stream" volume of vaccine (0.2ml ± 10%) through the epidermal layers of the skin.
Reconstitute the lyophilisate in the solvent or in Porcilis PCV ID as follows:

Lyophilisate	Solvent for Porcilis Lawsonia ID or Porcilis PCV ID
50 doses	10 ml
100 doses	20 ml

Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.

Special precautions for use in animals: Not applicable.
Safety and efficacy data, except for protection against mortality, are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed with Porcilis PCV ID. The product literature of Porcilis PCV ID should be consulted.
Shelf-life after reconstitution according to directions: 6 hours.

Composition: Each dose of 0.2 ml reconstituted vaccine contains:
Active substance (lyophilisate):
Inactivated Lawsonia intracellularis strain SPAH-08: ≥ 5323 U*
* Antigenic mass units as determined in the in vitro potency test (ELISA).
Adjuvant (solvent):

Paraffin, light liquid	8.3 mg
Dl-α-tocopheryl acetate	0.6 mg

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