Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	19C1.02
True Name	Salmonella Typhimurium Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro Megan Egg - Elanco US Inc. AviPro Megan Egg - Lohmann Animal Health International AviPro Megan Egg - No distributor specified Elanco US Inc. Lohmann Animal Health International
Date of Compilation Summary	February 20, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	*Salmonella* Typhimurium
Study Purpose	To demonstrate efficacy against *Salmonella enteritidis* for colonization of internal organs, ovaries, oviduct, intestinal tract, and ceca
Product Administration	Coarse spray
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 4, 2002

Study Type	Efficacy
Pertaining to	*Salmonella* Typhimurium, Δ *crp* Δ *cya* strain χ3985
Study Purpose	To demonstrate efficacy against *Salmonella* Typhimurium
Product Administration	One dose administered by coarse spray at 1 day of age and a second dose administered orally in the drinking water 3 weeks after first vaccination.
Study Animals	One hundred and eighteen (118) 1-day-old turkeys: 39 vaccinates, 39 placebo controls, 40 environmental controls
Challenge Description	Vaccinated and placebo controls were challenged with *Salmonella* Typhimurium 4 weeks after second vaccination.
Interval observed after challenge	Internal organ (liver and spleen) and intestinal tract (ileum and ceca) samples were evaluated on Day 7 post-challenge from all birds.
Results	A turkey was considered positive for *Salmonella* Typhimurium if identified by culture from tissues examined. Internal Organ (Liver and Spleen) Culture Results: Vaccinated group: 5/39 (12.8%) positive Placebo control group: 36/39 (92.3%) positive Environmental control group: 0/40 (0%) positive

Vaccinate ID	Internal Organs (liver and spleen)
1	-
2	-
3	-
4	-
5	-
6	-
7	-
8	-
9	-
10	-
11	-
12	-
13	-
14	-
15	-
16	-
17	-
18	-
19	-
20	-

21	-
22	-
23	+
24	-
25	-
26	-
27	-
28	+
29	+
30	-
31	-
32	+
33	-
34	-
35	-
36	+
37	-
38	-
39	-

Placebo Control ID	Internal Organs (liver and spleen)
1	+
2	+
3	+
4	+
5	+
6	+
7	+
8	+
9	+
10	+
11	+
12	+
13	+
14	+
15	-
16	+
17	+
18	+
19	-
20	+
21	+
22	+
23	+

	24 + 25 + 26 + 27 + 28 + 29 + 30 + 31 - 32 + 33 + 34 + 35 + 36 + 37 + 38 + 39 + Samples from all environmental controls were negative.
USDA Approval Date	January 8, 2016 and February 4, 2016

Study Type	Safety
Pertaining to	*Salmonella* Typhimurium
Study Purpose	To demonstrate safety under field conditions
Product Administration	Coarse spray
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 6, 2003

Study Type	Safety
Pertaining to	*Salmonella* Typhimurium
Study Purpose	To demonstrate safety under field conditions
Product Administration	Coarse spray and drinking water
Study Animals	Turkeys
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.