



## Summary of Studies Supporting USDA Product Licensure

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| Establishment Name  | Zoetis Inc.  |
| USDA Vet Biologics Establishment Number                                   | 190  |
| Product Code  | 1551.R0  |
| True Name   | Escherichia Coli Vaccine, Live Culture   |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | <small>Poulvac E. coli - Agrimatco Limited Algeria<br/>Poulvac E. coli - No distributor specified<br/>Poulvac E. coli - Not Listed<br/>Poulvac E. coli - SARL BIOLAB VETERINAIRE<br/>Poulvac E. coli - Zoetis Animal Health Ltd - Istanbul<br/>Poulvac E. coli - Zoetis Argentina<br/>Poulvac E. coli - Zoetis Australia Pty Ltd<br/>Poulvac E. coli - Zoetis Belgium SA<br/>Poulvac E. coli - Zoetis Colombia S.A.S.<br/>Poulvac E. coli - Zoetis Import Egypt<br/>Poulvac E. coli - Zoetis Industria de Produtos<br/>Poulvac E. coli - Zoetis Korea<br/>Poulvac E. coli - Zoetis Mexico<br/>Poulvac E. coli - Zoetis Russia<br/>Poulvac E. coli - Zoetis de Uruguay S.R.L.</small> |
| Date of Compilation Summary   | September 22, 2022   |

**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.**

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| <b>Study Type</b>                        | Efficacy  |
| <b>Pertaining to</b>                     | Escherichia coli  |
| <b>Study Purpose</b>                     | Demonstrate efficacy against <i>Escherichia coli</i>  |
| <b>Product Administration</b>            | Spray   |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             |   |
| <b>Interval observed after challenge</b> |   |
| <b>Results</b>                           | 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. |
| <b>USDA Approval Date</b>                | September 20, 2004  |

| <b>Study Type</b>                        | Efficacy  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
|--|---|--------------|---------------|--------------------|------------|-------|---------------------------------|--|--|--|--|-----------|--------------|---------------|--------------------|------------|-----------|------|------|------|------|------|---------|------|-------|-------|-------|-------|
| <b>Pertaining to</b>                     | Escherichia coli  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Study Purpose</b>                     | To determine efficacy against Escherichia coli  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Product Administration</b>            | Drinking water  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Study Animals</b>                     | Day-of-age chickens divided into 2 groups:<br>Group 1 vaccinated with product and challenged<br>Group 2 placebo vaccinated and challenged   |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Challenge Description</b>             | Virulent E. coli O78 given at 6 weeks of age  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Interval observed after challenge</b> | Observed daily until 7 days post-challenge  |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>Results</b>                           | <p>Vaccinates and controls were evaluated for signs of colibacillosis caused by Escherichia coli.</p> <table border="1"> <thead> <tr> <th rowspan="2">Group</th><th colspan="5"># birds positive / # challenged</th></tr> <tr> <th>mortality</th><th>pericarditis</th><th>perihepatitis</th><th>airsacculitis (as)</th><th>any lesion</th></tr> </thead> <tbody> <tr> <td>Vaccinate</td><td>0/28</td><td>4/28</td><td>2/28</td><td>5/28</td><td>5/28</td></tr> <tr> <td>Control</td><td>4/30</td><td>23/30</td><td>22/30</td><td>23/30</td><td>23/30</td></tr> </tbody> </table> <p>Raw data unavailable.</p> |              |               |                    |            | Group | # birds positive / # challenged |  |  |  |  | mortality | pericarditis | perihepatitis | airsacculitis (as) | any lesion | Vaccinate | 0/28 | 4/28 | 2/28 | 5/28 | 5/28 | Control | 4/30 | 23/30 | 22/30 | 23/30 | 23/30 |
| Group                                    | # birds positive / # challenged   |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
|  | mortality   | pericarditis | perihepatitis | airsacculitis (as) | any lesion |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| Vaccinate                                | 0/28  | 4/28         | 2/28          | 5/28               | 5/28       |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| Control                                  | 4/30  | 23/30        | 22/30         | 23/30              | 23/30      |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |
| <b>USDA Approval Date</b>                | February 22, 2010   |              |               |                    |            |       |                                 |  |  |  |  |           |              |               |                    |            |           |      |      |      |      |      |         |      |       |       |       |       |

|                                   |   |                                 |              |               |                    |            |
|-----------------------------------|---|---------------------------------|--------------|---------------|--------------------|------------|
| Study Type                        | Efficacy  |                                 |              |               |                    |            |
| Pertaining to                     | Escherichia coli  |                                 |              |               |                    |            |
| Study Purpose                     | To determine efficacy against Escherichia coli  |                                 |              |               |                    |            |
| Product Administration            | Coarse spray at 3 days of age and 3 weeks of age  |                                 |              |               |                    |            |
| Study Animals                     | Turkeys divided into 2 groups:<br>Group 1 vaccinated with product and challenged<br>Group 2 placebo vaccinated and challenged |                                 |              |               |                    |            |
| Challenge Description             | Virulent E. coli O78 given at 6 weeks of age  |                                 |              |               |                    |            |
| Interval observed after challenge | Observed until 7 days post-challenge.   |                                 |              |               |                    |            |
| Results                           | Vaccinates and controls were evaluated for signs of colibacillosis caused by Escherichia coli.                                |                                 |              |               |                    |            |
|                                   | Group   | # birds positive / # challenged |              |               |                    |            |
|                                   |   | mortality                       | pericarditis | perihepatitis | airsacculitis (as) | any lesion |
|                                   | Vaccinate   | 17/95                           | 57/95        | 17/95         | 57/95              | 58/95      |
|                                   | Control   | 27/94                           | 78/94        | 45/94         | 78/94              | 78/94      |
|                                   | Raw data unavailable.   |                                 |              |               |                    |            |
| USDA Approval Date                | February 22, 2010   |                                 |              |               |                    |            |

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| <b>Study Type</b>                        | Safety  |
| <b>Pertaining to</b>                     | All fractions   |
| <b>Study Purpose</b>                     | To demonstrate safety under field conditions  |
| <b>Product Administration</b>            |   |
| <b>Study Animals</b>                     | Chickens  |
| <b>Challenge Description</b>             |   |
| <b>Interval observed after challenge</b> |   |
| <b>Results</b>                           | 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. |
| <b>USDA Approval Date</b>                | February 24, 2006   |