



## **Elanco Ractopamine Background and Q&As Regarding EFSA Opinion**

### **Background:**

Ractopamine hydrochloride, or Ractopamine, is marketed under the trade names of Paylean® for swine and Optaflexx® for cattle. Paylean is a swine feed ingredient that directs nutrients to increase the amount of quality meat in high value cuts and improves production efficiency.<sup>1</sup> Paylean helps the pork industry meet consumer demand for safe wholesome pork products through increased carcass leanness, increased average daily gain and improved feed efficiency.<sup>2</sup>

Paylean was first approved for use in swine in December 1999 by the U.S. Food and Drug Administration; to date 26 regulatory authorities have registered Paylean. Ractopamine hydrochloride's safety profile allows for a zero day withdrawal time. It is estimated that more than 300 million pigs have been successfully marketed from Paylean feeding programs. Ractopamine Hydrochloride is the only compound from its class approved for swine production

Optaflexx is a feed ingredient fed to cattle during the final stage of the finishing period to increase live weight gain, improve feed efficiency and increase red meat yield.<sup>1,3</sup> Optaflexx delivers higher performance all the way to closeout and added benefits throughout the food chain. Its use maintains beef's natural taste, tenderness and juiciness with minimal impact on marbling score or quality grade. Optaflexx is delivered in the feed with no withdrawal period before marketing.

Elanco is a global research-based company that develops and markets products to improve the health and production of animals in more than 100 countries, with offices in more than 30 countries. Elanco is a division of Eli Lilly and Company, a leading innovation-driven pharmaceutical corporation. Elanco products enhance animal health, wellness, welfare and performance to help the food industry produce an abundant supply of safe and affordable food.

### **Questions and Answers:**

#### **Q. Which countries have determined that Ractopamine Hydrochloride (Ractopamine) is safe for use in swine and/or cattle?**

**A.** Twenty-six regulatory authorities have concluded that Ractopamine is safe and approved it for use in swine and/or cattle. These countries are: 1) in the Americas – Barbados, Bolivia, Brazil, Canada (pork and beef), Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico (pork and beef), Nicaragua, Panama, Peru, United States (pork and beef) and Venezuela; 2) in the Asia/Pacific area – Australia, Hong Kong, Indonesia, Malaysia, New Zealand, Philippines, South Africa, South Korea and Thailand. Also, Japan has established an ADI/MRL for pork and beef based upon a human food safety assessment.

#### **Q. What is the role of Codex?**

**A.** The Codex Alimentarius Commission (CAC or Codex), an international intergovernmental body under the United Nations, was established to protect the health of the consumer and facilitate trade. The CAC is the joint food standards program of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The CAC appoints a Joint FAO/WHO Expert Committee on Food Additives (JECFA) to provide expert advice to Codex on matters relating to food additives and residues of veterinary drugs in food. JECFA members are government or academic scientists who independently serve in their individual capacities as experts in the fields of toxicology and residue chemistry, and not as representatives of their governments or employers. Their goal is to establish safe levels of intake for humans and Maximum Residue Limits (MRLs) for veterinary drugs used in food animals in accordance with good veterinary practice.

**Q. What has been the timeline for the advancement of Ractopamine in the Codex process?**

- A.** Ractopamine hydrochloride has advanced by consensus at each Codex session:
- In February 2004, in Rome, Italy, the 62nd Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommended a ractopamine food safety standard for pork and beef.<sup>4,5</sup>
  - Ractopamine advanced to Step 4 at the October 2004 Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) meeting in Washington, D.C., USA.
  - Ractopamine advanced to Step 5 at the May 2006 CCRVDF meeting in Cancun, Mexico.
  - Ractopamine advanced to Step 6 at the July 2006 Codex Commission meeting in Geneva, Switzerland.
  - Ractopamine advanced to Step 8 at the September 2007 CCRVDF meeting in Breckenridge, Colorado, USA.
  - Ractopamine was held at Step 8 at the July 2008 Codex Commission meeting in Geneva, Switzerland in order to provide member states time to advance their risk assessments.

**Q. What is the history of beta-agonists in the European Union?**

**A.** Historically, the EU directive 96/22 bans (2003/74/EC) the use of beta-agonists for growth promotion uses in the EU and the import of meat from animals given such products. The purpose of the ban was to eliminate the unsafe and/or illegal use of beta-agonists within the EU. Specifically the directive notes, Member States shall prohibit the placing on the market of beta-agonists for administering to animals the flesh and products of which are intended for human consumption for purposes other than those provided for in the administering for therapeutic purposes of authorized veterinary medicinal products.<sup>6</sup>

**Q. What is the history of Ractopamine in the European Union?**

**A.** The EU ban was implemented without a full scientific assessment of Ractopamine, and subsequent extensive toxicology and human safety studies on Ractopamine have demonstrated its safety. Elanco and exporting countries have worked with the European

Commission regarding tracking measures to ensure compliance with EU desires. Elanco continues to work with producers, processors, packers and exporters to coordinate EU efforts.

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The label contains complete use information including cautions and warnings. Always read, understand and follow the label and use directions.

1. Elanco Data on File

2. Directions for use in swine: Feed at 4.5 to 9.0 g/ton to finishing swine in a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain (group average). Clinical registration studies showed no statistical difference between the effects of 4.5 g/ton and 9 g/ton. Caution: Ractopamine may increase the number of injured or fatigued pigs during marketing. Not for use in breeding swine.

3. Directions for use in cattle: Optaflexx is approved for feeding during the last 28 to 42 days prior to harvest to be fed at 8.2 to 24.6 g/ton to provide 70 to 430 mg/hd/d for the last 28 to 42 days on feed. For increased rate of weight gain, improved feed efficiency and increased carcass leanness feed Optaflexx during the last 28 to 42 days prior to harvest at 9.8 to 24.6 g/ton to provide 90 to 430 mg/hd/d. Caution: Not for animals intended for breeding.

4. 2004 WHO\_TRS\_925 [1] - 62<sup>nd</sup> JECFA – Ractopamine Review

5. Source: Reports of the 15<sup>th</sup>, 16<sup>th</sup> and 17<sup>th</sup> Sessions of the Codex Committee On Residues Of Veterinary Drugs In Foods and Reports of the 29<sup>th</sup>, 30<sup>th</sup> and 31<sup>st</sup> Session of the Codex Alimentarius Commission.  
[http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)

6. 31996L0022 Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists.

Paylean® is a trademark for Elanco's brand of ractopamine hydrochloride used in swine.  
Optaflexx® is a trademark for Elanco's brand of ractopamine hydrochloride used in cattle.

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