



REVIEW OF THE STATEMENT OF PRINCIPLE  
CONCERNING THE ROLE OF SCIENCE IN  
THE CODEX DECISION-MAKING PROCESS

*Case Approach – Zilpaterol MRLs in Codex*

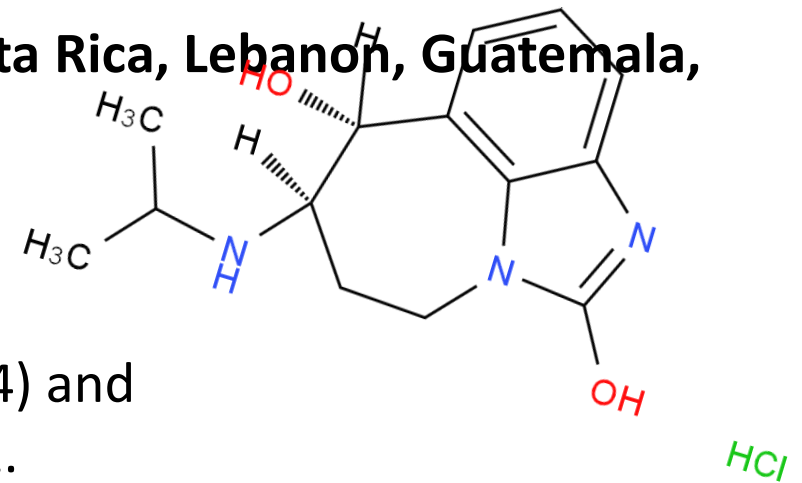
# The Issue

- ❑ Proposed MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) held at Step 4 at the last CCRVDF meeting (CCRVDF 25)
- ❑ It was deemed that the Standard Fulfilled all the requirements of Codex Standard Development:
  - Favorable evaluation by JECFA
  - Supportive Favorable Evaluations by other Food Safety Agencies such as EFSA
  - Extensive Discussions at CCRVDF: No technical Issue is impeding the development of the standard
- ❑ Linking the progress of this standard with the interpretation of the Statement of Principle and the Role of Science in Codex Decision-Making



# Background on Zilpaterol

- ❑ Zilpaterol hydrochloride (trade name Zilmax), CAS no. 119520-06-8), is a  $\beta$ 2-adrenoreceptor agonist that is used to **increase the rate of body weight gain**, improve feed efficiency and increase carcass muscle ratio in **cattle fed in confinement** before slaughter. Zilpaterol, by activation of protein kinase A, increases protein synthesis in skeletal muscle fibers, as well as reduces lipogenesis and increases lipolysis in adipose tissues.
- ❑ Zilpaterol is approved for use in several countries including: Canada, the USA, South Africa, South Korea, Mexico, Panama, the Ukraine and Brazil
- ❑ **Zilpaterol is mostly used / Sold South Africa, Mexico, Panama, Costa Rica, Lebanon, Guatemala, Honduras, Lesotho and Nicaragua**
- ❑ **Zilpaterol is not (much) used in the United States, Canada**
- ❑ Zilpaterol is not approved in China, Taiwan, Russia, and the EU
- ❑ Zilpaterol hydrochloride has been assessed by JECFA at its 78<sup>th</sup> (2014) and 81<sup>st</sup> (2015) meetings at the request of the CCRVDF21 and CCRCDF22.



# Zilpaterol at Codex



- ❑ JECFA Established Health Based Guidance Values for Zilpaterol:
  - ADI value of 0.04 ug/kg bw was set as the ARfD based
- ❑ EFSA (2016) noted that the ADI/ARfD of 0.04 µg/kg bw proposed by JECFA is **sufficiently protective for the establishment of MRLs and safe exposure levels for humans**” and considered JECFA’s evaluation as **“scientifically robust”**
- ❑ MRLs held at Step 4 at CCRVDF, while exhausting all the discussions
  - Opposition is not related to Science / Health issues but Policy considerations at the national or regional level
  - Mainly: **Directive 96/22/EC prohibits the use of β-agonists in food-producing animals except for therapeutic use, under direct veterinary supervision, in cows and horses.** Likewise, meat and meat products obtained from animals treated with β-agonist for growth promoting purposes are banned in the European Union.

# Positions Expressed

- ❑ During discussion on whether to hold zilpaterol at step 4 or advance to step 5
  - The EU despite stating they had no human health concerns objected to holding the MRL at step 4 or advancing it to step 5
  - EFSA had completed a review of the JECFA Risk Assessment and not only found it to be “robust” but also found no human health concerns and no animal welfare concerns at the recommended dosage
  - EU’s objection based on “consumer preference” and the fact that growth promoters are not allowed in the EU
- ❑ China objected to advancement as they stated that offal tissues are consumed in China and the MRL does not cover offal (muscle, fat liver and kidney per Procedural Manual)
- ❑ Russia objected saying that Russia had additional data (never submitted)
  - CCRVDF has a Concern Form that delegations can submit if they have data or human health concerns for JECFA’s review. No Submission was made in relation with zilpaterol



# Status in CCRVDF

- ❑ The Chair of CCRVDF based on the fact there were objections to holding Zilpaterol at step 4 or advancing it to step 5 sought advice from CCEXEC
- ❑ The question was on Course of Action when the objections were not based on science, were not within the mandate of Codex
  - A minority of delegations objected to the discussion



# Discussions at CCEXEC

- ❑ CCEXEC discussed the situation that had taken place at CCRVDF and decided that Chairs needed advice on how to apply the Statements of Principle
- ❑ A subcommittee of the CCEXEC was formed, Chaired by Vice Chair Raj Rajaseker from New Zealand and an EWG was set up to begin discussion
- ❑ The Chair of the subcommittee issued a report of progress to the CCEXEC that contained a preamble describing the discussion and various options and with a decision tree
- ❑ CCEXEC is still discussing the issue but has refined it down to the decision tree as a guide for Chairs and has also said that it will be provided to delegates



# What is the Issue ... And Impacts on the Region

## ❑ Facts:

- Scientific Evaluation of Zilpaterol is supportive of the adoption of MRLs at Codex
- A standard Adopted at Codex does not mean that countries have to adopt it – The substance can still be not allowed in the countries that have the rationale to do so
- A codex Standard would support countries that decide to use Zilpaterol to set safe levels for its use
- Zilpaterol is not used in the US, Canada – and has no impacts on these countries exports – Impact on South-South Trade

❑ Issue: Can countries impose their national policies on Codex / at the international level

❑ Question of Principle to uphold Codex Principles and Precedent Setting





