



SW Pacific
CODEX

THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS

Case Approach – Zilpaterol MRLs in Codex

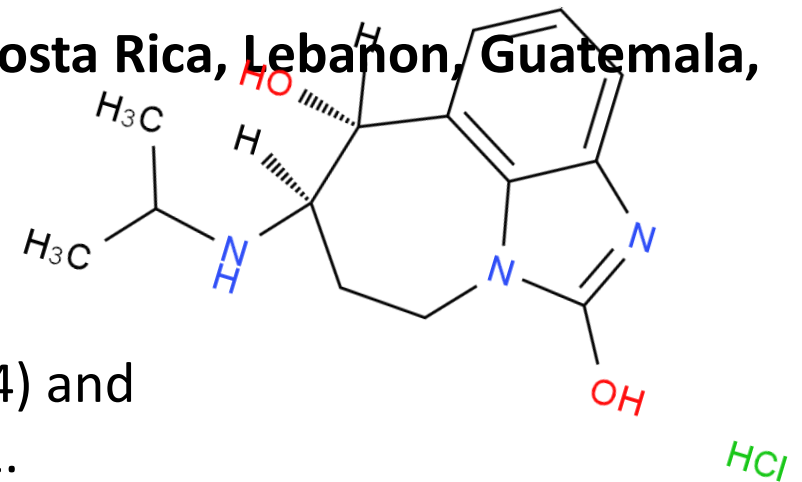
The Issue

- ❑ 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 β 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 in 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 78th (2014) and 81st (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



A word cloud featuring the phrase "Thank You" in numerous languages. The words are arranged in a circular pattern, with "thank you" in the center in a large, bold, blue font. Other prominent words include "danke" (German), "teşekkür ederim" (Turkish), "gracias" (Spanish), "bedankt" (Dutch), "dziękuję" (Polish), "obrigado" (Portuguese), "merci" (French), "terima kasih" (Indonesian), "sukriya" (Arabic), "go raibh maith agat" (Irish), "mochchakkeram" (Bengali), "tapadh leat" (Welsh), "ngiyabonga" (Xhosa), "rahmat" (Arabic), "spas" (Slovene), "tack" (Swedish), "barka" (Somali), "welalin" (Hausa), "misaotra" (Malagasy), "matondo" (Zulu), "paldies" (Latvian), "grazzi" (Italian), "mahalo" (Hawaiian), "xhala" (Xhosa), "asante" (Swahili), "manana" (Hawaiian), "tenki" (Japanese), "chokrane" (Bengali), "murakoze" (Bengali), "mamnun" (Urdu), "dijere dieuf" (Afrikaans), "tau" (Hawaiian), "дякую" (Ukrainian), "sulpáy" (Quechua), "go raibh maith agat" (Irish), "arigatō" (Japanese), "tak" (Tibetan), "dakujem" (Slovak), "trugarez" (Breton), "merci" (French), "dhanyavadagalu" (Kannada), "shukriya" (Urdu), "merce" (Catalan), "мерси" (Russian), "xiexie" (Chinese), "감사합니다" 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