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

Case Approach – Zilpaterol MRLs in Codex

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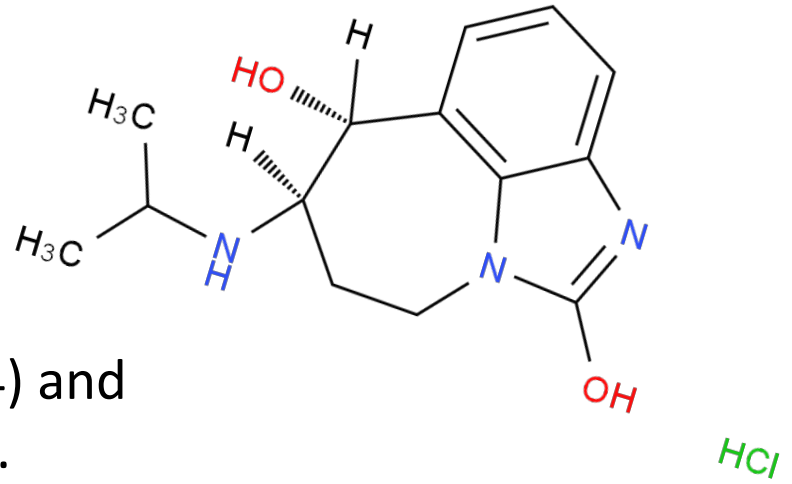
The Issue

- 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 β2-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, the Ukraine and Brazil**
- **Zilpaterol is mostly used / Sold in South Africa, Costa Rica, Mexico, Lebanon**
- **Zilpaterol is not (much) used in the United States, Canada**
- Zilpateroll 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 Assesment 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

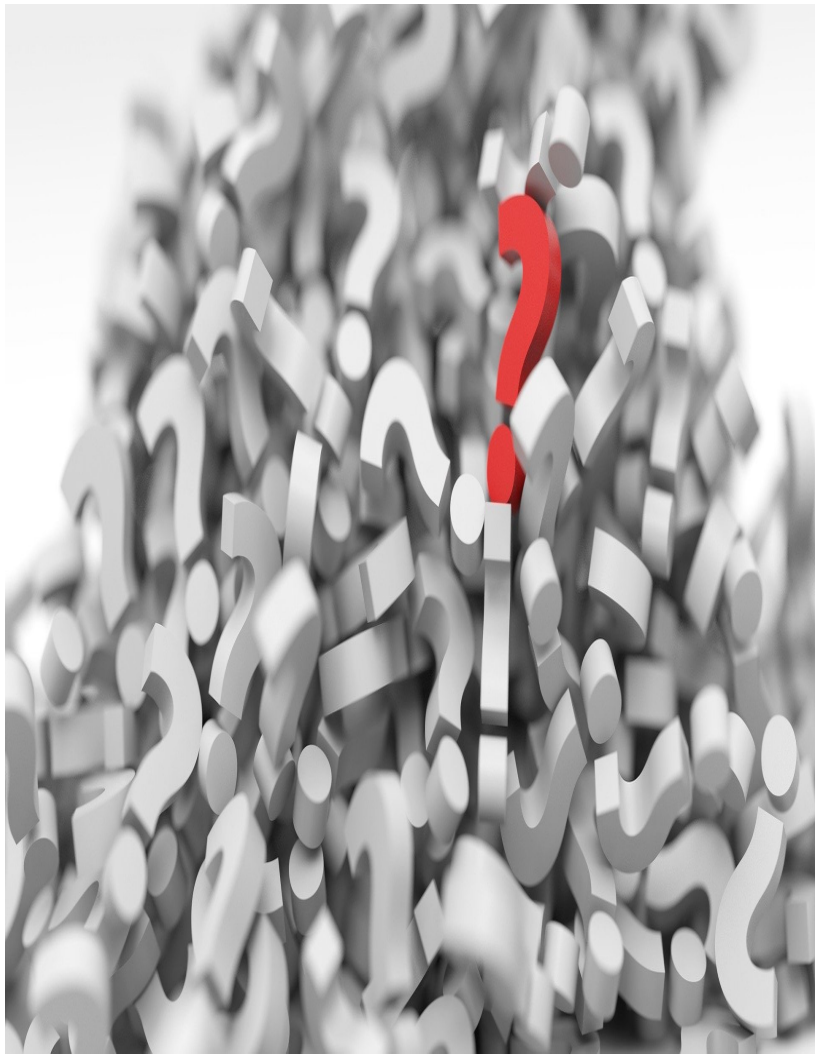
- The Chair of CCRVDF based on the fact there were objections to holding Zilpaterol at step 4 or advancing it to step 5 sought advice from CCEXEC
- The question was on Course of Action when the objections were not based on science, were not within the mandate of Codex
  - A minority of delegations objected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

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