CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 4.8 **CRD16**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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Comments of NHF on Zilpaterol Hydrochloride

(CX/EXEC 22/83/2 Add.2 of Agenda Item 2: Critical Review Part 3 (zilpaterol))

The National Health Federation (NHF), a non-profit consumer organization, respectfully submits the following comments on the draft MRLs for Zilpaterol hydrochloride for consideration at CAC45:

Safety Issues for Zilpaterol Still Exist

The reason that there is significant **sustained opposition** to a Zilpaterol MRL is because growth promoters like Zilpaterol do not belong in animal-health husbandry:

- Growth-promoting substances do not belong in animal husbandry and many food companies – including Tyson and Merck itself – have had their own concerns about Zilpaterol causing health and behavioral problems with cattle (with Cargill/Merck even having pulled the product off the market in 2015).
- Countries such as China and Thailand have correctly pointed out that further safety and scientific data are required for Zilpaterol residues in offal tissues (see, e.g., Thailand's excellent CRD4 from CAC44 and this year's CRD7).
- Zilpaterol's **use in horses has already been banned**, so why are we trying to use it in cattle?
- Being a catecholamine, Zilpaterol has been implicated as a contributory cause for increased bacterial problems coming off commercial feedlots.
- No risk assessment of this dangerous chemical compound has been done in connection with other vet drugs and chemicals so there is no data on the cumulative and synergistic effects on humans or animals from the drug residues of Zilpaterol and other drugs and chemicals acting together.
- The residues in food can impact humans even at the levels currently determined by JECFA to be safe, causing tremors, heart palpitations, and other health issues.
- Consumers have the right to know and choose what they are consuming and Zilpaterol residues violate that right since they are not declared on the food.
- Given all of these problems with Zilpaterol, NHF would like to hear from Merck, the sponsor of this drug, how Zilpaterol aligns with its Environmental, Social, and Governance (ESG) goals [especially given Merck's announced commitment to the Precautionary Principle on page 14 of its ESG Progress Report].

No Risk Assessment Has Been Done Per Codex Procedural Manual

The Codex Procedural Manual very clearly states that: **"Risk assessment should be based on realistic exposure scenarios."** (See Section IV, Risk Analysis, 2(e)) This means that one or more risk assessments should have been done on Zilpaterol's synergistic effects with the other drugs, toxins, endocrine disruptors, hormones, and chemicals that animals and humans are directly exposed to in the real world. **This was not done.**

Instead**,** risk assessments were conducted addressing Zilpaterol risk in isolation. That is not a "realistic exposure scenario" in today's world where we are all bombarded not only with numerous chemicals and biological substances but also electromagnetic influences.

So, contrary to all of the claims made at CAC44 and CAC45 that Zilpaterol has been the subject of "robust" risk assessments, CAC45 actually does not have the scientific support for Zilpaterol safety that has been claimed for it.

No Consensus

Whether Codex delegates agree with NHF or not on the safety issue, one other insurmountable obstacle to advancement of the Zilpaterol MRLs is absolutely and irrefutably clear and that is that **there is No Consensus**:

- Consensus is defined as "the absence of sustained opposition."
- There has most definitely been longstanding, sustained opposition to the Zilpaterol MRLs from the European Union, Norway, Switzerland, Russia, China, Kazakhstan, Thailand, Saudi Arabia, Iran, Turkey, Ukraine, and Kyrgyzstan. Codex cannot ignore the strong opposition of a considerable portion of the World's population here!
- Claims of ***"scientific consensus"*** are without legal foundation as there is absolutely nothing in the Codex Procedural Manual to support such a narrowed view of consensus. The CPM simply says "consensus."
- Codex is the sole Risk Manager here, so it is entirely appropriate for it to accept or reject any risk assessment, for any reason whatsoever.
- Not every standard is meant to go forward. It is ***never*** a defeat for Codex to consider a standard and then decide that – upon reflection – this would not be the way to go forward. Real Science is challenge and debate and reconsideration. Real Science is not blindly moving forward "because we have to" or "because otherwise we will look bad." Codex will only project a bad image if we fail to challenge, correct, and even stop a standard when that standard fails to meet our procedural and other requirements.
- Without consensus, not even CCEXEC can advance the MRLs forward, particularly when they were only asked for advice and not action by CCRVDF25.
- If CCEXEC acts in some sort of STAR CHAMBER capacity to unilaterally advance the MRLs to Step 5 (or even a very unwise Step 5/8) while disregarding the obvious lack of consensus, then CCEXEC and CAC are operating in violation of the Codex Procedural Manual.
- It was NHF's understanding from the opinion expressed at the previous CAC meeting (CAC44) by Codex Legal Counsel Claudia Nannini to the delegates on November 12, 2021, that CAC may not be able to come to a conclusion on this matter and that it should be postponed. This supports NHF's position that there is no consensus, and her advice should be followed.

No Voting

There may be some member states that will call for a vote on these MRLs at CAC45, which is ***highly disfavored*** as a procedural move. As everyone here knows, the Codex Procedural Manual calls for guidelines and standards to advance towards adoption based upon the consensus of the members present.

- Do not forget the very destructive fight over Ractopamine at the Rome meeting in July 2012, which led to several influential delegations angrily threatening to leave Codex! We do not want a repeat of that here!
- And if CAC45 shoves this standard down the World's throats, this could happen again, maybe not at CAC45 but certainly when Step 8 adoption is debated.
- NHF supports and echoes Egypt's call in its CRD12 for CAC45 to avoid voting on this issue if at all possible.

Conclusion

The MRLs for Zilpaterol cannot be advanced at all for at least two major reasons:

1. No risk assessment based on ***realistic*** exposure scenarios has been conducted on Zilpaterol residues in accordance with the Codex Procedural Manual, so safety issues for this veterinary drug are still in question; and
2. No consensus exists at CAC45 to advance the MRLs to Step 5.

Codex either follows its own rules and procedures or else it is a lawless organization deserving of no respect. In the face of such sustained opposition (i.e., "no consensus"), CAC45 only has two choices here – no matter how many of its delegates might wish otherwise – it can either discontinue work on this standard or it can keep it at Step 4. CAC45 has zero right to advance this standard to Step 5 and doing so in these circumstances would greatly damage or even destroy Codex's credibility.

Moreover, it constantly amazes NHF that Zilpaterol – which is not therapeutic in any way, indeed it harms many animals, and is only intended to increase drug sales – has elicited such fierce support from certain Codex delegates. We remind everyone that the motto of Codex after all is "Safe, Good Food for Everyone" and not "More Sales for Industry."