

**Appendix IX****STATEMENTS ON ADOPTION AT STEP 5 OF DRAFT MRLs FOR  
ZILPATEROL HYDROCHLORIDE IN CATTLE LIVER, KIDNEY AND MUSCLE*****Statements received in writing:*****European Union**

The EU reiterates its strong opposition to the adoption of the MRLs for zilpaterol by the Commission. As zilpaterol is solely used for the purpose of growth promotion, the EU cannot not support an international standard that endorses its use. The EU has systematically opposed the development of Codex MRLs for growth promoters. The EU opposition to growth promoters is based on concerns about the health and welfare of animals, consumer preferences, and moral and socio-economic concerns about the sustainability of farming practices that employ growth promoters. The One Health approach also recognizes the interlinkages between these different aspects and the health of consumers.

The EU policy on such substances is widely supported by European citizens and it is applied in a non-discriminatory manner. The EU upholds the core Codex values of inclusiveness, collaboration, consensus building and transparency. Unfortunately, consensus has never been reached in Codex on the question of growth promoters due to divergent conceptions and expectations regarding food production systems. This is in sharp contrast with the rest of Codex work since Codex has successfully adopted thousands of standards and other Codex texts by consensus. The EU remains strongly committed to Codex work and trusts that in the future similar situations can be avoided by ensuring consensus on the amenability of certain standards at the start of the work, allowing the focus of our precious resources on genuine needs and issues of global relevance. The EU is looking forward to discuss this topic at the next CAC, in full respect of the applicable rules of procedure. The EU is grateful to the chair of the Commission for the very precious procedural guidance and clarification provided before this CAC and for his skillful handling of our discussions in line with the rules. The EU remains open to engage in further consensus seeking on this issue in the run-up to CAC46.

**Norway**

Norway voted against the adoption at Step 5 because we would have preferred a consensus decision which might have suited all parties, both for us that strongly oppose the MRLs and for those in need for MRLs. We still consider it important that Members engage further in discussions to find consensus in order to avoid a vote at Step 8 at the next Commission.

**Thailand**

The decision to adopt MRLs for zilpaterol hydrochloride at Step 5 was not taken by consensus. Thailand is concerned that with high consumption of edible offal tissues, including those other than liver and kidney, the risk posed to consumers may include effect of residues from the current recommended use and withdrawal period of zilpaterol hydrochloride and cause adverse health effect of exposure. In this regard, we believe the exposure assessment has not been done completely. In addition, the national policy and regulations in Thailand only allow the use of veterinary drugs for therapeutic purposes, not for the other objectives, such as growth promotion. For these reasons, Thailand would like to reserve its position on the adoption of MRLs for zilpaterol hydrochloride at Step 5.

**United Kingdom**

The United Kingdom maintained its opposition and abstained from acceptance of the decision to adopt MRLs for zilpaterol hydrochloride at Step 5 as this compound is prohibited in national legislation. The United Kingdom further noted that the decision to adopt the zilpaterol MRLs at Step 5 was reached by vote and not consensus.

**United States of America**

The United States welcomes the adoption of MRLs for zilpaterol at Step 5 and commends the Commission and its Members for coming together to advance this work. To meet the global challenge of ensuring the availability and affordability of safe food to every country, community, and household, we must embrace innovation and science. In this spirit, the United States will continue to call on the Commission and Codex Members to uphold the institution's foundations by advancing international standards that are based on science and that serve the collective interests of global consumers and producers. If Codex is to fulfill its mandate, zilpaterol standards must move forward for final adoption at CAC46.

***Statements based upon the transcript of CAC45:*****Argentina**

We would like to congratulate the Chairperson for the work carried out. Not because we actually approved zilpaterol, which was the task at hand but for having applied the Procedural Manual and not having continued to prolong the discussion on this matter because this might have been easier and more comfortable. So, we congratulate you on that. I'm worried that there was no reaction to any of the things that were said because it seems that some people have morals and others don't. And I don't know if there's a bar here that's been set on morality. And why do we have to discuss morality in this forum? Here we need to talk about science, we need to talk about results, and we need to be conscious of the fact that it is impossible for 180 countries and their communities to have the same concerns, because obviously it would be denying the world's many different cultures. Talking about the concerns of consumers is not realistic because consumers are extremely diverse and have very different concerns throughout the globe. And so, there are issues that out of respect should not be used here. We've known for years and years, ever since we started discussing these matters, that none of these issues are legitimate or within the legitimate scope of Codex. They are just opinions that are prolonging the debate. It is detrimental to Codex when we postpone a decision for 20 years and do not apply the Procedural Manual.

**Chad**

Thank you for guiding us in these discussions and seeing us through the vote regarding zilpaterol, which is a growth hormone. And as has been said, there have been discussions based on scientific data. I think that we should not leave it at the vote, but we should pursue the discussion regarding risk analysis in order to go deeper into risk management and also communication on risk and therefore the use of zilpaterol.

**Chairperson of CCRVDF**

I wish to express my gratitude to the Members of this Commission for their extensive discussion on the draft MRLs for zilpaterol. As Members noted, the CCRVDF has also thoroughly discussed the draft MRLs during several sessions. The discussion of the MRLs for zilpaterol has been a challenging one, on which there are strongly held views on both sides. As this Commission did, CCRVDF was able to reach consensus on the JECFA risk assessment basis of the MRLs. But the CCRVDF has been unable to reach consensus on any action for the MRLs. The CCRVDF could neither agree to advance nor to hold them. It is always preferable to make decisions based on consensus, but I greatly appreciate the willingness of this Commission to make decisions by other means deemed appropriate. In particular, I thank the Members of this Commission for making decisions that CCRVDF has been unable to make. And lastly, I'm grateful to the Commission for your support and agreement to retain the future discussion of the draft zilpaterol MRLs within the Commission.

**Chile**

Chile would like to thank you for the efforts carried out in order to make headway on this matter. We'd like to recall what we said yesterday. As defined in the principles of risk assessment, in the case of zilpaterol, we also would like to recall that the form for presenting information is always there. And that's why we support what was said by Uruguay, the United States of America, and Ecuador. And Chile would like to make sure that this statement is recorded in the report.

**China**

We would like to congratulate you on your leadership and on your efforts. However, we do regret the decision that's been taken considering zilpaterol, because it is a substance that is forbidden in many countries. It is a growth promoter that does not meet with consensus. We cannot predict the risks, especially in edible offal. We don't know what kind of hazards exist in that context. We did advance the standard to Step 6. We regret that, and we'd like for our reservation to be recorded.

**Ecuador**

We endorse what was just expressed by the United States of America and Uruguay and we accept, of course, the outcome of the vote. We believe that all decisions of Codex Alimentarius ought to be based on science and on the principles of risk assessment. If there are no scientific reasons contrary to the recommendations made by the expert committee, and if there are no other legitimate factors that ought to be considered globally, then they should not influence on our risk management or the attainment of consensus. We believe that there was a consensus to advance. So, we voted, we decided on things, and we're going to continue to work. We ask that our statement be recorded as it was delivered in the report.

**Indonesia**

As we stated on the first day, Indonesian regulation does not approve the use of growth promoters including zilpaterol hydrochloride. Obviously, Indonesia also respects the result of the voting for the proposal on MRLs yesterday and noted that the decision made has been concluded by the Commission. With that, Indonesia would like to register its reservation for this issue.

**Kazakhstan**

Kazakhstan would like to echo other countries who have objected to the adoption of the MRL for zilpaterol. I would like to note that consumers in Kazakhstan also consume other edible offals. We need an inclusive approach in assessing the safety of zilpaterol.

As we can see, that the problem we face is the lack of additional scientific data or other factors. Discussion showed that in many countries the use of growth promoters is forbidden, and therefore it cannot be stated that we will have full data in the near future.

This raises a logical question – why should we approve at the international level the MRLs for these promoters? Austria and Norway have well noted that the risk assessment is carried out by JECFA, but we are the ones who make the decision, in other words, the Commission.

And therefore, once again Kazakhstan would like to take the opportunity to call on countries to pay attention to the very serious nature of this matter.

**Russian Federation**

We vote against the adoption of the standard and we are also against the use of growth promoters, and zilpaterol is one of these. As we proposed earlier, to leave the discussion at Step 4 and to put an end to the discussion because we are unable to reach consensus on this matter. We also pointed out that the scientific data have not been seen through to their conclusion, including the major or chronic impact that this can have on the population. You set out the concrete steps whereby we could take the matter further yesterday, and over the past two days, many countries have said that they do not make use of zilpaterol in their own countries and yet they voted for adoption of the standard. Many of these countries spoke about the WTO and these countries can, between now and the next session, discuss how they will fulfil their obligations vis a vis that particular organization. Of course, the Codex standards are not mandatory, they are recommendations. But nobody has put an end to obligations under the WTO. So, the standard has been left at Step 6. This is not the result that we would have liked to see. But we agree that the matter remains at Step 6 and that going further, we should move along the guidelines, the directives of Codex.

**Saudi Arabia**

We would like to thank you for your efforts. Saudi Arabia has reservation regarding the adoption of this standard at Step 5 as we do not agree with using growth promoters. That is why we would like to record our reservation.

**Uganda**

Uganda would like to reecho our submission that we made yesterday. And following the outcome of the decision which was made, we would like to support the progression that was made in terms of moving forward with this particular issue. Although I would have loved to close the matter once and for all in this Commission, which may not have been possible. We are happy to note that we made a step forward and we should be able to keep progressing. We do not think that there would be any difference in terms of the weight of the standard regardless of the method that has been deployed considering that the option is fully available in the Codex Procedural Manual and the application of the standard would not be hindered precisely because of the methodology that was adopted in terms of progression. We would further appeal to the Commission to get the subject out of the way as soon as it could. And in any case, probably in the upcoming session, such that we are able to further engage on other important matters of the Commission.

**Uruguay**

Uruguay would like to thank the Chairperson for making such great efforts to try to find a satisfactory solution to this problem. There are diverging opinions about voting in Codex. For us voting is a mechanism contained in our statutes and it's a viable way of executively solving a problem that's been drawn out over time. So we reiterate our opinion, which we expressed previously, i.e. a vote in this situation was the right solution. There was agreement that the absence of consensus was based on the existence of objections that are founded on the very tenets of Codex; science and fair trade and safety of consumers. Considering objections that are not within the remit of Codex, as viable, is not good practice. Simply because somebody is against, it doesn't mean that there's no consensus. There is no consensus when there is a divergence with the foundations of the body in question.

**Zimbabwe**

Zimbabwe thanks the Chairperson profusely for the patience to continue to pursue these remarks this morning. Yesterday it was asked one question, to say, do all Members have an equal voice in Codex? And today, in my mind, I think that question still remains. Just two days ago, we had a matter, a conscientious matter. And we solved it amicably through your able leadership, Chairperson, having noted the discontentment among many, many, many countries on the aflatoxins discourse. We submit that the aflatoxins have deleterious effects on people, the majority of these victims being in Zimbabwe or in Africa, in similar countries. The matter did not receive as much attention as we are now having on zilpaterol, where we are flagging animal welfare issues. Animal welfare and the health of the people. Animal welfare and the health of the people. And I must repeat the last time; Animal welfare having pre-eminence above the health of an entire continent. So, I would like to congratulate you, Chairperson. I don't envy your job at all. You worked so hard. You nudged us to get a step forward. We are only unhappy that we were not able to get to a full adoption of these MRL's, but we are happy that we moved some steps. So, we stand with the United States of America, Uganda, Chile, Uruguay, the list is endless, in support of an accelerated adoption of MRLs for zilpaterol. And I think CAC46 will finalize this job.