CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX ALIMENTARIUS COMMISSION

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COMMENTS AT STEP 6 ON THE DRAFT MRLS FOR ZILPATEROL HYDROCHLORIDE IN CATTLE LIVER, KIDNEY AND MUSCLE

(Comments in reply to CL 2023/33/OCS-CAC)

Comments of Argentina, Australia, Brazil, Cambodia, Canada, Chile, Costa Rica, Cuba, Ecuador, European Union, Gambia, Honduras, Indonesia, Iran, Iraq, Jordan, Kazakhstan, Kenya, Mauritius, Mexico, Morocco, New Zealand, Norway, Panama, Paraguay, Peru, Republic of Korea, Senegal, Switzerland, Thailand, United Arab Emirates, Uganda, United Kingdom, Uruguay and United States of America

BACKGROUND

1. This document compiles the comments at Step 6 on the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle. The comments are those received through the Codex Online Commenting System (OCS), or via email by the time this document was issued. The comments are as shown in Appendix I.

2. OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardized way, thus providing more transparency and better management of comments on different Codex texts as requested through circular letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex committees.

EXPLANATORY NOTES ON APPENDIX I

3. The comments received are presented in a table format, with two columns as follows:

    - First column – Presents the comments with the rationale.
    - Second column – Presents the provider of the comments (name of country or observer)

APPENDIX I

GENERAL COMMENTS

COMMENTS	MEMBER/OBSERVER
Argentina apoya el avance a trámite 8 para la adopción definitiva por parte de la Comisión de los LMR de Zilpaterol para hígado, riñón y músculo bovino recomendados por el comité. Argentina, apoya las decisiones y conclusiones del Codex basadas en ciencia.	**Argentina**
Australia supports the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle being adopted at Step 8. There has been no reason identified, within the Codex mandate, including throughout successive rounds of informal consultations, that would support holding the work, suspending the work, or redefining the scope of the work. We see no scientific or procedural reason why CAC46 should not advance the draft MRLs to final adoption. We also note CRD02 submitted by the FAO/WHO JECFA Secretariat to CAC45, which explains the basis of the JECFA evaluation, including why MRLs for additional edible offals have not been set. We feel this explanation provides clarity to members concerned about MRLs for additional edible offals (other than liver and kidney) with regard to the procedural way forward to have these considered; and that it should not hold up adoption of the draft MRLs in liver, kidney and muscle.	**Australia**
Brazil supports advancing the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscleto Step 8. It is important to highlight that numerous risk assessments have been carried out over these years by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), based on solid scientific data available, and no safety concerns have been associated with the use of Zilpaterol Hydrochloride. Likewise, no Codex member has submitted to CCRVDF, JECFA or CAC any additional data or scientific evidence demonstrating any adverse effects in terms of food safety at recommended limits (MRL 3.5 µg/kg for liver, 3 .3 µg/kg for kidney and 0.5 µg/kg of muscle in cattle). It is essential that Codex bases its decisions on scientific approaches and that its standards have a worldwide reach. No domestic politics of any kind should interfere with the standard setting process, to preserve the clarity, transparency and predictability of Codex procedures. Paragraph 4 of the Statements of Principles states that members may abstain from accepting a certain standard, without this necessarily preventing Codex from adopting its decision. Having this in mind and considering that the proposed standard has a robust scientific basis, as well as the broad support needed to move forward, Brazil is in favor of advancing the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle to Step 8. Once again, we highlight that factors outside the Codex mandate should not interfere with the risk management process. Decisions should be based on risk assessment, taking into account, where appropriate, other legitimate factors that are within the Codex mandate and that are relevant to the protection of consumer health and the promotion of fair practices in the food trade, as indicated in the Procedural Manual	**Brazil**
Cambodia has no objection on these draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle.	**Cambodia**

Canada appreciates the opportunity to comment on CL 2023/33/OCS-CAC. Canada continues to support the establishment of international standards for veterinary drugs on the basis of credible scientific evidence, regardless of the status of authorization of that particular drug in individual countries. Canada recognizes and re-affirms the respect it holds for the scientific evaluation conducted by the Joint FAO/WHO Expert Committee on Food Additives as it relates to human health considerations which demonstrated that there are no public health or scientific concerns for the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney, and muscle. Canada is of the view that the draft MRLs for zilpaterol hydrochloride have met all the procedural and scientific requirements for advancement. As such, Canada continues to support the final adoption of the draft MRLs for zilpaterol hydrochloride at Step 8.	**Canada**
Hasta el momento no hemos tenido noticias de algún miembro haya presentado información adicional y no hay claridad que miembros que han planteado preocupaciones diversas en las reuniones del comité, hubiesen aportado información relevante y de sustento para tener en cuenta por lo tanto Chile apoya el avance a tramite 6, respalda la evaluación realizada por JECFA y los LMR propuestos en hígado, riñón y músculo de vacuno.	**Chile**
Comentarios específicos: Como parte de las consultas especificas en esta CL Costa Rica quisiera ratifica su apoyo al avance de los LMR tal como lo recomienda el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA). Es decir: Especie Tejido LMR (µg/kg) Bovino Riñón 3,3 Bovino Hígado 3,5 Bovino Músculo 0,5 Justificación: El JECFA en su 85ª reunión, evaluó los datos y concluyó que los datos de biodisponibilidad adicionales facilitados apoyan el enfoque utilizado en la evaluación previa y tras la evaluación de los datos adicionales, los LMR recomendados por el JECFA en su 81ª reunión se mantuvieron sin modificaciones. Cabe mencionar que, a la fecha se han realizado 3 evaluaciones con la misma información disponible. Por lo anterior, se considera que todos los procedimientos de evaluación establecido por el Codex Alimentarius para el desarrollo de este anteproyecto se han cumplido, toda la información científica disponible y aportada por los miembros para el clorhidrato de Zilpaterol ha sido considerada por el JECFA y no se ha manifestado a la fecha, interés por parte de algún miembro en ninguna de las sesiones celebradas por el CCRVDF, CCEXE y la CAC para presentar nuevos datos científicos disponibles que justifiquen una nueva evaluación por parte del JECFA. Costa Rica es del criterio que este tema se ha mantenido más del tiempo requerido en las agendas del CCRVDF y la CAC y como ya se mencionó que en tanto no haya disponibilidad de nuevos datos, no se visualiza una nueva evaluación por parte del JECFA. Por consiguiente, si no se aprobaban los LMR propuestos, los países deberán establecer sus propios LMR contribuyendo de esta manera a la desarmonización del comercio. Por lo expuesto, considera trascendental que la CAC en su 46ª periodo de sesiones apruebe la propuesta al trámite 8 con la inclusión de la	**Costa Rica**

siguiente aclaración: Se solicitará una nueva evaluación al JECFA inmediatamente después de que un miembro presente su interés de aportar nuevos datos. Posibles implicaciones del proyecto de norma en sus intereses económicos. En cuanto a las implicaciones puntuales del proyecto de norma en términos económicos, no se visualiza ningún impacto dado que a nivel país ya se cuenta con un LMR de referencia. No obstante, Costa Rica es del criterio que, contar con un LMR para el Clorhidrato de Zilpaterol aprobado por un organismo internacional como lo es el Codex Alimentarius, que además es el ente de referencia de la Organización Mundial del Comercio (OMC) en materia de legislación de alimentos por ser el organismo internacional que brinda las pautas que rigen el comercio y la protección de la salud del consumidor, les permite a sus miembros realizar sus registros de productos veterinarios bajo un contexto técnico sólido y científicamente sustentado. Conclusión: Para Costa Rica el apoyo a la adopción de los LMR para el Clorhidrato de Zilpaterol en esta ocasión no radica en el impacto positivo o negativo que pueda generar su adopción o no. En su efecto, el apoyo que como país miembro se ha manifestado a lo largo de estos años en diferentes intervenciones y CRDs corresponde al acatamiento a los lineamientos establecidos en el Manual de Procedimiento y el reconocimiento al principio científico. El no permitir el avance de un LMR para cualquier sustancia que ya cuenta con sólido estudio científico sin una justificación debidamente sustentada, aporte de nuevos datos o información adicional sobre preocupaciones que pueden ser abordadas por el Codex en el marco de sus competencias, representa un riesgo para otras sustancias que podrían no tener del todo un LMR por el Codex. Asimismo, podría generar un grave precedente con respecto a la credibilidad en la gestión y el futuro del Codex Alimentarius como organismo de referencia mundial. Es mucho lo que está en juego a la hora de proteger la salud de los consumidores y asegurar la adopción de prácticas leales en el comercio alimentario.	
Cuba apoya los LMR propuestos por el Codex, porque se basan en la ciencia	**Cuba**
1. Ecuador apoya la adopción de los Límites Máximos de Residuos (LMR) para el Clorhidrato de Zilpaterol (grasa, riñón, hígado y músculo de bovinos) en el Trámite 8. Basamos este apoyo en las múltiples evaluaciones de riesgos realizadas por el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA), en cuyo hallazgos científicos se fundamentan la toma de decisiones del Codex, así como la adhesión al Manual de Procedimiento del Codex el doble mandato del Codex de centrarse en proteger la Salud de los consumidores y asegurar prácticas equitativas en el comercio de los alimentos. 2. La mayoría de los miembros votó en el 45.o Periodo de Sesiones de la Comisión del Codex (CAC45), a favor de la adopción de los LMR para el Clorhidrato de Zilpaterol (grasa, riñón, hígado y músculo de bovinos) en el Trámite 5 y, sobre la base de los procedimientos del Codex, los LMR se circularían para recabar comentarios en trámite 6, para examen de CAC46 en trámite 7 y considerar su adopción en el Trámite 8 por la CAC46 (REP22/CAC párrafo 139, 140). 3. Destacamos las evaluaciones de riesgos que a lo largo de los años (REP15/RVDF, párr. 40, REP17/RVDF, párr. 74) ha llevado a cabo	**Ecuador**

el JECFA, basadas en los sólidos datos científicos disponibles, en las que no se han identificado problemas de seguridad asociados al uso del Clorhidrato de Zilpaterol; así como el hecho de que ningún miembro del Codex ha presentado al CCRVDF o al JECFA datos o pruebas científicas adicionales, que demuestren efectos nocivos para la seguridad alimentaria a las dosis recomendadas (LMR de 3,5 µg/kg para hígado, 3,3 µg/kg para riñón y 0,5 µg/kg de músculo en bovinos). 4. Aunque se proporcionaron datos adicionales al JECFA en su 85ª reunión (2017) tras la evaluación del JECFA, se concluyó que los datos adicionales de biodisponibilidad proporcionados apoyan el enfoque utilizado en la evaluación anterior y, recomendó que los LMR se mantuvieran sin cambios con respecto a las conclusiones de la evaluación de riesgos realizada por el JECFA en 2015 (81ª reunión del JECFA). 5. En la CAC45, la Secretaría del JECFA explicó que los valores orientativos basados en la salud para el Zilpaterol se basaban en el parámetro toxicológico más sensible, que, en este caso concreto, se encuentra en los efectos agudos. Además, la dosis aguda de referencia se basó en los resultados obtenidos en voluntarios humanos, lo que constituye una prueba muy sólida de la máxima confianza. (REP22_CAC párrafo 108). 6. Como se ha mencionado, el Codex Alimentarius es el organismo de referencia mundial para los consumidores, los productores y los procesadores de alimentos y contribuye claramente con sus recomendaciones al proceso regulador nacional, así como al comercio internacional. Desempeña un papel importante en calidad e inocuidad de los alimentos en todo el mundo, especialmente para aquellos países en desarrollo y menos desarrollados que no cuentan con la infraestructura necesaria, o los recursos económicos para generar suficiente apoyo científico para las medidas sanitarias nacionales o regionales. 7. Limitar el avance de un proyecto de norma para el establecimiento de un LMR sin aportar ningún dato científico socava el trabajo del comité y del Codex en su conjunto, ya que ignora y no respeta el procedimiento para la aprobación de normas, que se basan, como en este caso, en las evaluaciones realizadas por el JECFA, que es el Grupo de Expertos independientes que realizan las evaluaciones de riesgo de aditivos, contaminantes y medicamentos veterinarios, que proporcionan las evaluaciones de riesgo que garantizan que las normas del Codex cumplan con sus objetivos y estén basadas en toda la información científica disponible. Del mismo modo, nos preocupa el impacto negativo en el proceso de armonización internacional que estos reiterados retrasos sin evidencia científica y la introducción de factores sin la debida justificación científica acordes al mandato del Codex están teniendo en la adopción de las normas del Codex, lo que podría afectar a la credibilidad del Codex como organismo de referencia en materia de calidad e inocuidad alimentaria. 8. Observamos que el párrafo 4 de las Declaraciones de Principios establece que "Si se da la situación de que los Miembros del Codex están de acuerdo en el grado de protección de la salud pública necesario, pero tienen opiniones diferentes sobre otros aspectos, los Miembros pueden abstenerse de aceptar la norma en cuestión, sin que ello impida necesariamente que el Codex adopte su decisión". Con esto en mente, y teniendo en cuenta que la norma propuesta para el establecimiento de LMR para el Clorhidrato de Zilpaterol tiene una base científica que respalda su uso como norma de referencia en el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias (MSF) de la Organización Mundial del Comercio (OMC), confirmamos que existe un amplio apoyo para adelantar este anteproyecto de norma al Trámite 8. 9. Los factores sin la debida justificación científica acordes al mandato del Codex no deberían influir en la gestión de riesgos para lograr el consenso. Las decisiones deben basarse en la evaluación de riesgos y/o el análisis de los beneficios a la salud, teniendo en cuenta, cuando proceda, otros factores legítimos que estén dentro del mandato del Codex y que sean pertinentes para la protección de la salud de los	

consumidores y la promoción de prácticas leales en el comercio de alimentos, como se indica en el Manual de Procedimiento. Recomendación 10. Basándose en las conclusiones y recomendaciones de los diversos informes del JECFA relativos a la evaluación de riesgos y en el hecho de que los países que se oponen al avance no han presentado ni sustentado con la debida justificación científica acorde al mandato Codex su oposición, los países mencionados solicitan a la 46ª Comisión del Codex Alimentarius, que se celebrará en noviembre y diciembre de 2023, que adopte el LMR para el Clorhidrato de Zilpaterol en el Trámite 8.	
The European Union (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 is opposed to 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 recognises the interlinkages between these different aspects and the health of consumers. Therefore, the use of growth promoters is not allowed in Europe. The EU does neither authorize nor accept import of meat derived from animals that were administered with the substances. 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 recalls its strong commitment to an ambitious Codex Alimentarius fit for the challenges of today and tomorrow, as stated by the Council conclusions adopted by the EU member states in 2022. The EU is dedicated to maintaining its collaboration with all Codex members and observers, and its effective contribution to the Codex Alimentarius in all its dimensions. In that perspective, the EU remains open to engage in further consensus seeking on this issue in the run-up to and at CAC46.	**European Union**
The Gambia Position of the Request for comments at step 6 on the draft MRLs for zilpaterol hydrochloride in cattle Cognizant of the fact that JECFA derived an Acute Reference Dose and an Acceptable Daily Intake of 0.04 lg/kg body weight (per day) based on neurological effects seen in humans and, after carrying out an exposure assessment and has recommended maximum residue limits (MRLs) for zilpaterol in cattle of 3.3 lg/kg in kidney, 3.5 lg/kg in liver and 0.5 lg/kg in muscle, The Gambia generally considered the approach followed by JECFA for setting MRLs for zilpaterol to be scientifically robust. It is clear that in The Gambia, zilpaterol is not widely used in the production of animals and the country do not have the technical, infrastructural and procedural capacity to determine the level of zilpaterol animal products. Thus, to have a global standard based on the proposed recommended MRLs which are anchored on the risk assessment conducted by scientifically credible institution like JECFA will be helpful in guiding and controlling the use of zilpaterol in animal production. Considering that The Gambia is challenged with food insecurity and malnutrition and the fact that the country can only produce half of its food	**Gambia**

consumption requirement especially beef and its products, their importation therefore is critical in ensuring food and nutrition security. Thus, the country submits its acceptance of the position on the adoption of Zilpaterol Hydrochloride at Step 8. However, to facilitate enforcement and control of the use of zilpaterol, The Gambia will need technical, infrastructural and procedural support to build its capacity to determine the level of zilpaterol animal products. The country will also strengthen the protection and promotion of animal welfare in the country and beyond.	
Honduras agradece la oportunidad de presentar comentarios al proyecto de LMR del clorhidrato de Zilpaterol en hígado, riñón y músculo de vacuno. Respaldamos las evaluaciones de riesgo realizadas por el JECFA basadas en los sólidos datos científicos disponibles, en las que no se han identificado problemas de inocuidad alimentaria asociados al uso de esta sustancia en bovinos. El Codex Alimentarius ha sido el organismo de referencia mundial que establece normas de inocuidad y calidad alimentarias para proteger la salud de los consumidores y las prácticas equitativas en el comercio en los últimos 60 años. Además, ha desempeñado un rol fundamental para proporcionar normas basadas en ciencia especialmente para países en vía de desarrollo como el nuestro que no cuentan con la infraestructura necesaria para establecer LMRs que permitan proteger nuestras poblaciones, promover la seguridad alimentaria y facilitar el comercio local e internacional. Expresamos nuestra preocupación de las intenciones de algunos miembros de limitar el avance de este proyecto aun cuando la evaluación de riesgos de JECFA es robusta y no existen datos adicionales que pueda rebatir las recomendaciones del Grupo de Expertos ya que esto podría tener un impacto negativo en el proceso de armonización internacional y afectar la credibilidad y continuidad del Codex como el organismo de referencia a nivel internacional en materia de inocuidad y calidad alimentaria. Es por ello, que Honduras apoya la adopción en Trámite 8 de los límites máximos de residuos (LMR) del Clorhidrato de Zilpaterol y exhorta a CAC46 a basar su proceso de decisión en las conclusiones y recomendaciones de la evaluación de riesgos de JECFA para continuar respaldando el trabajo científico de los Grupos de Expertos y asegurar la continuidad del Codex como el organismo internacional de referencia en normas alimentarias.	**Honduras**
Indonesia noted that CAC45 agreed that the JECFA risk assessment provided a robust basis for the elaboration of MRLs for zilpaterol hydrochloride. However, Indonesia would like to reiterate our position regarding MRLs for zilpaterol. Indonesia would like to express our abstention from acceptance of the MRL Zilpaterol without necessarily preventing the decision by Codex. Indonesia noted that the issue of zilpaterol has been discussed by Codex for a long time, and we strongly encourage that the next CAC meeting can provide a final conclusion on this work. This is important to maintain the credibility of Codex as an internationally recognized standard-setting body and Codex standards as a reference point in the international food trade, and not to get dragged into uncertainty about the working status of this zilpaterol.	**Indonesia**
1. According to our survey on literature, it is clear that zilpaterol has some adverse effects in human. Thus, we have concerns about side effects of zilpaterol in consumers. As, European Food Safety Authority (EFSA) in a scientific report in toxicological evaluation section (3.1.1) also mentioned that “in human studies with healthy volunteers, a single oral dose of 3.6l µg zilpaterol/kg bw resulted in cardiovascular effects and increased blood glucose levels. Repeated application of 11.04l µg zilpaterol/kg bw per day not only lead to cardiovascular effects but also induced tremors and bronchodilatation. Similarly, treatment of asthmatic patients with a single dose of 3.86l µg/kg bw increased bronchodilatation and heart rate and decreased diastolic blood pressure. In addition, finger tremors were observed. In asthmatic patients	**Iran**

receiving three single oral doses of 1.52l µg zilpaterol/kgbw, bronchodilatation was seen while 3.79l µg zilpaterol/kg bw also affected heart rate. Mild, but clinically relevant tremor was observed in two patients at single doses of 0.76 and 1.52l µg /kg bw, and in eight patients at 3.79l µg/kg bw". 2. We are also of the opinion that with regard to the lack of scientific data about adverse effects of zilpaterol in human, it is necessary to perform more investigations to deny its carcinogenicity. 3. In addition to carcinogenicity, studies must perform to evaluate teratogenicity and mutagenicity of zilpaterol. 4. All in all, offal such as liver, lung, and kidney are consumed a lot in Iran and we have concerns about health issues. Therefore, we strongly believe that MRL in liver and kidney should be less than 3.5 µg/kg in liver and 3.53 µg/kg in kidney. 5. As you know, MRL for clenbuterol is 0.2, 0.6 and 0.6 µg/kg for muscle, liver and kidney, respectively. Clenbuterol and zilpaterol are Beta2-adrenergic agonists The reason of these suggestions is that scientific data about side effects of zilpaterol in human in not enough for scientific society. Therefore, we have to be more cautious Cattle Muscle 0.1 Cattle Kidney 0.5 Cattle Liver 0.5	
We are Preventing growth promoter in animals	**Iraq**
Jordan does not allow growth promoters and has no intention to change its policy - Jordan supports the adoption of the standard because it fulfils all the requirements of Codex standard setting. This will allow countries that allow this substance to have safe conditions of use. This support from Jordan does not mean an acceptance of Zilpaterol in Jordan's national food regulations.	**Jordan**
Kazakhstan continues to object to the adoption of the MRLs.	**Kazakhstan**
Comment Kenya acknowledges the results of JECFA risk assessment report of Zilpaterol hydrochloride in that it poses insignificant risk to human health. However, Kenya abstains from acceptance of the adoption of the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle without necessarily preventing its advancement. Kenya would like to register reservations on the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle. Rationale Kenya does not approve the use of Zilpaterol hydrochloride in cattle due to other considerations including economic and animal welfare. Economically, farmers who use growth hormones for livestock production can have an unfair advantage of lowered cost of production over farmers who rear conventionally as the hormones shorten the time the animals spend on farm before sale. Additionally, adopting the MRLs may be perceived wrongly by meat consumers who may worry about eating imported meat from animals reared using growth hormones. These consumers can boycott eating meat which will affect our economy negatively. On animal welfare, growth hormones cause the animals to gain weight much faster than their bodies can carry. This can cause stress to the animal due to pain experienced in carrying excess weight. There are reports from elsewhere of animals who were reared using growth hormones taken to the slaughterhouses without hooves. Reason being the hooves could not bear the weight of the animals.	**Kenya**
The use of Veterinary medicinal products such as zilpaterol hydrochloride for the purpose of growth promotion in cattle is not allowed in Mauritius for the purpose of maintaining the confidence of consumers.	**Mauritius**

The use of any growth promoting agent in the livestock industry is in itself a matter of concern from an ethical perspective and a consumer protection point of view notwithstanding the position of the livestock industry which advocates for the use of such products to maintain competitiveness of the industry.	
La posición nacional a favor de mantener y aprobar la propuesta de LMR para zilpaterol en riñón, hígado y músculo de bovino, en Trámite 6, con objeto de ser aprobado en Trámite 8 en la próxima sesión plenaria.	**Mexico**
Le Maroc n'a pas d'objection pour l'adoption des LMR proposées à la prochaine session de la Commission CAC 46	**Morocco**
New Zealand (NZ) appreciates the opportunity to comment on CL 2023/33/OCS-CAC the 'Request for comments at step 6 on the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle that was adopted at Step 5 by CAC45 (by vote)'. NZ supports the adoption at Step 8 of MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle as a matter of principle. All decisions in Codex should be made on the basis of sound scientific evidence and risk analysis principles – a founding tenet of Codex - to ensure the development of robust standards that embody Codex's dual mandate to protect the health of consumers and ensure fair practices in food trade. NZ considers no reason has been identified, within the Codex mandate, which would support not adopting this work. Furthermore, failure for CAC46 to adopt zilpaterol at Step 8 may create a negative precedent in terms of maintaining science as the basis for Codex decisions on future standards with respect to Codex's mandate to protect the health of consumers. Furthermore, NZ recognises the robust scientific evaluation conducted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) demonstrating that there are no public health or scientific concerns. Thorough and independent scientific risk assessments concluded that zilpaterol residues, when present at or below the proposed MRLs, pose no food safety concerns, and therefore recommended that the proposed zilpaterol MRLs be adopted by Codex. We note that there is broad consensus among Codex members on the robustness and acceptability of the JECFA evaluation of zilpaterol in terms of food safety and consumer health protection. The European Food Safety Authority (EFSA) conducted a review of the JECFA risk assessment and found no human health concerns; additionally, it noted that there was no evidence of animal welfare concerns at the recommended dosage (while noting animal welfare concerns are outside the mandate of Codex). With respect to Codex's mandate to ensure fair practices in the food trade, zilpaterol is being used primarily in developing countries. It is our understanding that the largest user is South Africa where it has been in use for over 20 years, followed by Mexico, Panama, Costa Rica, Guatemala, Honduras, Lebanon, Lesotho, and Nicaragua. Many of these countries adopt Codex standards for domestic use, as do their trading partners and export markets. Without a Codex MRL they may not have an MRL or risk assessment to provide a safe level for use as their national legislation and domestic standards rely on Codex standards. We consider that the use of zilpaterol without a Codex MRL may not provide the necessary level of protection in developing countries where it is primarily used. Furthermore, we consider a failure to finalise the zilpaterol MRLs at CAC46 may undermine Codex's credibility as the WTO's international reference organization for food safety standards.	**New Zealand**

We believe all relevant issues have been fully considered and other factors raised are not relevant in Codex. We see no procedural reasons that would prevent a decision by CAC46 to advance zilpaterol to Step 8. Furthermore, it is important for Codex to uphold its rules and agreed processes in decision making. NZ would prefer that the decision not to go to vote. However, if CAC46 does proceed to a vote, consideration must be given to participation by members of the South West Pacific (SWP) region who do not have a representative in Rome and may not be able to physically attend CAC46.	
When it comes to growth promoters in general, it has been established by now that there is no global consensus (on the risk management) and therefore no harmonization is foreseen. It is our view that Codex should either avoid placing them on the agenda or discuss other risk management options than global standards. In the case of growth promoters MRLs will not be globally accepted, therefore Codex should not spend any more time and resources on these specific substances. Codex has during its RM discussions clarified that there is substantial disagreement on whether or not to adopt MRLs, For transparency this should be clearly identified in the output.	**Norway**
Regarding the economic impact, Panama to date allows the use of the growth promoter “Zilpaterol”, we have had no problems, however it is necessary to have a reference regulation that supports us in regulating the market. It does not represent a major economic effect. At all times we will use international references validated by science to justify an approval or rejection. Regarding the economic impact, Panama to date allows the use of the growth promoter “Zilpaterol”, we have had no problems, however it is necessary to have a reference regulation that supports us in regulating the market. Science has supported the study that JEFCA has presented, we believe in the work developed. Panama, like many countries, depends on reference organizations such as the Codex Alimentarius for the establishment of MRLs for veterinary drugs, which are part of the process and evaluation in the authorization of compounds for use at the national level. It does not represent a major economic effect. At all times we will use international references validated by science to justify an approval or rejection. En cuanto al impacto económico, Panamá hasta la fecha permite el uso del promotor de crecimiento “Zilpaterol”, no hemos tenido inconvenientes, sin embargo es necesario contar con una normativa de referencia que nos apoye en la regulación en el mercado. No representa un efecto económico de mayor importancia. En todo momento utilizaremos referencias internacionales validadas ante la ciencia para justificar una aprobación o rechazo. En cuanto al impacto económico, Panamá hasta la fecha permite el uso del promotor de crecimiento “Zilpaterol”, no hemos tenido inconvenientes, sin embargo es necesario contar con una normativa de referencia que nos apoye en la regulación en el mercado. La ciencia ha respaldado el estudio que JEFCA ha presentado, creemos en el trabajo desarrollado. Panamá al igual que muchos países depende de organizaciones de referencia como el Codex Alimentarius para el establecimiento de los LMR de los medicamentos veterinarios, lo cuales son parte del proceso y evaluación en la autorización de los compuestos para su uso en el ámbito nacional. No representa un efecto económico de mayor importancia. En todo momento utilizaremos referencias internacionales validadas ante la ciencia para justificar una aprobación o rechazo. Panama reiterates its support for the approval of the MRLs for Zilpaterol Hydrochloride, in liver, kidney and muscle. It has been a historic debate and well justified by research organizations such as JECFA, all avenues of consultation have been exhausted. We have recommended in several meetings, CCRVDF, and CAC the support of approval and progress to the following procedures. All Codex decisions must be based on	**Panama**

science and risk assessment principles. It is clear that there are no scientific reasons against the recommendation made by JECFA, nor are there other legitimate factors that should be considered worldwide. In this regard, factors outside the Codex mandate should not influence risk management to achieve consensus. Considering that the MRL proposal for Zilpaterol Hydrochloride has a scientific basis that supports its use as reference standards in the WTO SPS Agreement, we confirm that the MRL proposal must now be approved at step 6. Panama reiterates its support for the approval of the MRLs for Zilpaterol Hydrochloride, in liver, kidney and muscle. It has been a historic debate and well justified by research organizations such as JECFA, all avenues of consultation have been exhausted. We have recommended in several meetings, CCRVDF, and CAC the support of approval and progress to the following procedures. All Codex decisions must be based on science and risk assessment principles. It is clear that there are no scientific reasons against the recommendation made by JECFA, nor are there other legitimate factors that should be considered worldwide. In this regard, factors outside the Codex mandate should not influence risk management to achieve consensus. Considering that the MRL proposal for Zilpaterol Hydrochloride has a scientific basis that supports its use as reference standards in the WTO SPS Agreement, we confirm that the MRL proposal must now be approved at step 6. Panamá reitera, el apoyo a la aprobación de los LMR para Clorhidrato de Zilpaterol, en hígado, riñón y músculo. Ha sido un debate histórico y bien justificado por los organismos de investigación como JECFA, se han agotado todas las vías de consulta. Hemos recomendado en varias reuniones, CCRVDF, y CAC el respaldo de aprobación y avance a los siguientes trámites. Todas las decisiones del Codex deben basarse en la ciencia y en los principios de evaluación de riesgos. Es claro que no existen razones científicas contrarias a la recomendación hecha por el JECFA, ni existen otros factores legítimos que deban ser considerados a nivel mundial. En este sentido, los factores fuera del mandato del Codex no deberían influir en la gestión de riesgos para lograr el consenso. Considerando que la propuesta de LMR para el Clorhidrato de Zilpaterol tiene una base científica que respalda su uso como estándares de referencia en el Acuerdo MSF de la OMC, ratificamos que la propuesta de LMR debe ser aprobada ahora en su trámite 8. Panamá reitera, el apoyo a la aprobación de los LMR para Clorhidrato de Zilpaterol, en hígado, riñón y músculo. Ha sido un debate histórico y bien justificado por los organismos de investigación como JECFA, se han agotado todas las vías de consulta. Hemos recomendado en varias reuniones, CCRVDF, y CAC el respaldo de aprobación y avance a los siguientes trámites. Todas las decisiones del Codex deben basarse en la ciencia y en los principios de evaluación de riesgos. Es claro que no existen razones científicas contrarias a la recomendación hecha por el JECFA, ni existen otros factores legítimos que deban ser considerados a nivel mundial. En este sentido, los factores fuera del mandato del Codex no deberían influir en la gestión de riesgos para lograr el consenso. Considerando que la propuesta de LMR para el Clorhidrato de Zilpaterol tiene una base científica que respalda su uso como estándares de referencia en el Acuerdo MSF de la OMC, ratificamos que la propuesta de LMR debe ser aprobada ahora en su trámite 8.	
Paraguay no objeta los límites propuestos para los LRM del Clorhidrato de zilpaterol para hígado, riñón y músculo, por lo tanto apoya su avance, teniendo en cuenta que hasta la fecha no se tienen nuevos datos.	**Paraguay**
No se tienen observaciones en el trámite 6 sobre el proyecto de LMR del clorhidrato de zilpaterol en hígado, riñón y músculo de vacuno	**Peru**
Korea supports the draft MRLs for zilpaterol hydrochloride, which are based on the scientific evaluation by JECFA, aligning with our previously reiterated stance at CCRVDF.	**Republic of Korea**
Position : Le Sénégal soutient l'adoption finale de la proposition de LMR pour le chlorhydrate de zilpatérol (foie, rein et muscle de bovins) Contexte et Justification : Les LMRS pour le chlorhydrate de zilpaterol ont été adoptées à l'étape 5 par un processus de vote en 2022 a la CAC45 pour les tissus	**Senegal**

suivants chez le bovin : • Rognons 3,3 µg/kg • Foie 3,5 µg/kg • Muscle 0,5 µg/kg Les mêmes LMRS sont soumis aux membres pour commentaires à l'étape 6. Le Sénégal rappelle, par le CRD15 du point 4.8 de l'ordre de du jour de la CAC45, qu'il a déjà exposé les motifs de sa position. D'autant plus que c'est un pays en développement qui a besoin d'une norme Codex sur laquelle, il pourrait s'appuyer pour réglementer la sécurité des produits importés ce qui constitue une assurance pour garantir la santé de sa population. Aussi, le Sénégal réaffirme son attachement o aux résultats issus des évaluations scientifiques de JECFA qui donnent tout son sens lorsque l'on dit que le Codex est le seul organe qui élabore ses normes sur une base scientifique et qui sont reconnues par l'Organisation Mondiale du Commerce (OMC) o aux règles de procédure du Codex, et en particulier les énoncés de principe, indiquent clairement que le Codex doit (devrait) fonder ses (les) normes sur des bases (normes) scientifiques. Les facteurs non scientifiques et autres préoccupations hors du mandat du Codex ne devraient pas être prises en compte lors de l'établissement des normes. La déclaration de principes (paragraphe 4) stipule que « …les membres peuvent s'abstenir d'accepter la norme établie sans nécessairement bloquer la décision du Codex ». Conclusion Le Sénégal s'inscrit dans la recherche de solution par consensus pour l'adoption `de la norme. Aussi en s'appuyant sur toutes les déclarations ci-dessus, la proposition pour les commentaires à l'étape 6 est de sauter l'étape 7 et d'adopter les LMRS à l'étape 8 fixées pour le chlorhydrate de Zilpaterol dans les reins, le foie et les muscles de bovins.	
The development of MRLs for growth promoters is by far the most long-standing and divisive topic in Codex as no global consensus on the risk management side has been found. In Switzerland's view Codex should not spend more time and resources on MRLs for growth promoters (including zilpaterol hydrochloride) as there will be no global acceptance for these substances.	**Switzerland**
Thailand opposes the adoption of the draft MRLs for zilpaterol hydrochloride in cattle liver, kidney and muscle with the rationale mentioned in Appendix IX of REP22/CAC. Although the decision to adopt the MRLs at Step 5 was taken by voting, Thailand emphasizes the crucial significance of consensus in the development of Codex texts. The Commission should attempt to find consensus on the consideration of the MRLs by applying the guidance of operationalization of SoP, especially the uses and approaches to apply SoP4. Thailand supports Option 2 – Use of footnotes in standard to acknowledge the use of SoP4. Therefore, if the draft guidance could be finalized with allowance to record the use of Statement 4 as footnotes in standard, Thailand believes that it could contribute to the decision of some member countries on the issues of MRLs adoption. In relation to the implications of the draft standard, it consequence of economic interest may arise from the risk communication aspect. Specifically, the ability of the national government to effectively engage with both consumers and producers may be hindered, resulting in challenges to mitigate the confusion arising from disparities between Codex MRLs and domestic regulations.	**Thailand**
UAE is very thankful to the chair of the Commission for his efforts in handling this matter in line with codex guidelines and procedures. UAE citizens are highly consuming imported meat and edible offal tissues at the same time zilpaterol hydrochloride is prohibited in national legislation. UAE team will continue searching and studying any related updates.	**United Arab Emirates**

Based on the sound risk assessment undertaken by JECFA on the compound, propose adoption at the current stage and subsequent progression through the final stages of development in order to conclude discussions on the MRLs at CAC46.	**Uganda**
Our position remains that we do not support and are opposed to the standard for zilpaterol and our intention remains to express our continued opposition procedurally through abstention of acceptance of the standard, so as not to prevent a decision. However, we also maintain that in the extremely rare situations like zilpaterol, where a significant number of members steadfastly maintain their opposition to the standard (40% of votes cast against), that the SoP guidance should enable the inclusion of a footnote to the standard to record members' opposition in a transparent way. Please therefore also refer to our more detailed comments on this in [response to CL 2023/32/OCS-CAC]. Furthermore, the UK takes the view that finding a consensual way forward on zilpaterol that provides the necessary clarity and assurances to the significant number of members opposed to the standard provides a template for the future on how to reach a decision in the absence of a global consensus without the need to resort to a vote.	**United Kingdom**
Uruguay no tiene observaciones respecto a los limites propuestos. En relación a las posibles implicaciones del proyecto de norma en sus intereses económicos, Uruguay entiende que esta consideración se realiza en etapas previas, al aprobar el comienzo del trabajo de establecimiento de limites de residuos del medicamento, por lo que en la actual etapa (trámite 6) no es pertinente.	**Uruguay**
The United States urges all Codex members to support adoption of the proposed MRLs for Zilpaterol hydrochloride (kidney, liver, and muscle of cattle) at Step 8 at the 46th session of the Codex Alimentarius Commission (CAC46) taking place in November 2023. This support should be based on the multiple risk assessments conducted by the independent FAO / WHO Joint Expert Committee on Food Additives (JECFA), the scientific underpinning of Codex decision making, as well as adherence to the Codex Procedural Manual and the mandate of Codex to focus on human food safety and ensuring fair trade practices. An overwhelming majority of members voted at CAC45 (November 2022) to adopt the MRLs for zilpaterol (kidney, liver and muscle of cattle) at Step 5, and based on Codex procedures the MRLs are now at Step 7 for consideration at Step 8 by CAC46 (2023). We highlight the risk assessments (REP15/RVDF, para. 40, REP17/RVDF, para. 74) that have been carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) over the years, based on the solid scientific data available, in which no food safety concerns associated with the use of zilpaterol have been identified and established; as well as the fact that no Codex member has submitted to the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) any additional data or scientific evidence demonstrating any harmful effects to food safety at the recommended doses (MRL of 3.5 µg/kg for liver, 3.3 µg/kg for kidney and 0.5 µg/kg muscle in cattle) or a concern form as allowed for in the procedures of CCRVDF. Additional bioavailability data was provided to JECFA at its 85th session (2017), and JECFA concluded the additional data reaffirms the approach used in its previous evaluations and recommended the MRLs remain unchanged from the levels determined by JECFA in 2015 (81st JECFA). At CAC45 (2022) the JECFA Secretariat explained the health-based guidance values for zilpaterol considered the most sensitive toxicological endpoint, which, in this specific case, is applied to acute effects. Furthermore, the acute reference dose was established based on results obtained from human volunteers, which constitutes very strong evidence of the highest confidence (REP22_CAC para 108).	**United States of America**

Limiting the progress of a draft standard for the establishment of an MRL without providing any scientific data undermines the work of the committee and of Codex as a whole and ignores the procedure for the approval of standards, which is based, as in this case, on the evaluations made by JECFA — the independent Group of Experts that carry out risk assessments for veterinary drug residue in food and thus ensure that Codex standards are safe and based on all the scientific information available. Similarly, we are concerned about the negative impacts that these repeated delays without scientific evidence and introduction of factors outside of the Codex mandate are having on the adoption of Codex standards, which could affect the credibility of Codex as an international standard setting body for food safety. We note that paragraph 4 of the Statements of Principles Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account in the Codex Procedural Manual states that "When the situation arises where Codex Members agree on the necessary level of public health, but hold differing views about other considerations, members may abstain from acceptance of the relevant standard, without necessarily preventing the decision by Codex." As all members have affirmed their confidence in JECFA and the zilpaterol risk assessment, those countries who object to establishment to an MRL for other reasons should simply file a reservation as called for in the procedures and have the rational for their reservation captured in the report. They should not prevent the countries that need an MRL to protect public health from having one. Factors outside the Codex mandate should not influence risk management decisions in Codex. Decisions should be based on the independent JECFA risk assessment and those other legitimate factors that are within the Codex mandate and that are relevant to the protection of consumer health and the promotion of fair practices in the food trade, as indicated in the Procedural Manual.	