Contacto CONAMER GLS-CVLS-AMMDL-B0002320/2

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Asunto:	Comentarios de la Industria Farmacéutica Veterinaria al Acuerdo que declara al territorio de los Estados Unidos Mexicanos, como libre de Influenza Aviar Tipo A Subtipo H5N1
Datos adjuntos:	Comentarios al Acuerdo ZL IA-Industria Farmaceutica Veterinaria.pdf

COMISIÓN NACIONAL DE MEJORA REGULATORIA P R E S E N T E.

En representación de la Industria Farmacéutica Veterinaria de la Cámara Nacional de la Industria Farmacéutica, me permito presentar en tiempo y forma nuestros comentarios al Proyecto de "Acuerdo por el que se declara al territorio de los Estados Unidos Mexicanos, como libre de Influenza Aviar Tipo A Subtipo H5N1", publicado en portal de anteproyectos de la Comisión Nacional de Mejora Regulatoria, el 29 de agosto del 2023.

Agradeciendo de antemano el apoyo en la consideración y publicación de estos en el portal de Anteproyectos de esa Comisión, le envío un cordial saludo.

Atentamente



Ing. Rocío Reyes Pérez Jiménez Directora Ejecutiva Industria Farmacéutica Veterinaria (INFARVET)

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Ciudad de México, a 1 de septiembre de 2023

Asunto: Comentarios de la Industria Farmacéutica Veterinaria al Acuerdo por el que se declara al territorio de los Estados Unidos Mexicanos, como Zona Libre de Influenza Aviar Tipo A, Subtipo H5N1

COMISIÓN NACIONAL DE MEJORA REGULATORIA P R E S E N T E.

La Industria Farmacéutica Veterinaria de la Cámara Nacional de la Industria Farmacéutica, en representación de sus integrantes y con base en nuestro enfoque de Responsabilidad Social, que nos orienta a contribuir a la sanidad y bienestar animal y humano, participando así en la producción de proteína animal destinada a la alimentación de los mexicanos, ponemos a consideración los siguientes comentarios al Proyecto de "Acuerdo por el que se declara al territorio de los Estados Unidos Mexicanos, como libre de Influenza Aviar Tipo A Subtipo H5N1", publicado en portal de anteproyectos de la Comisión Nacional de Mejora Regulatoria, el 29 de agosto del 2023, tomando en cuenta que:

- 1. En años recientes, nuestro país ha padecido varios brotes de influenza aviar tanto del virus tipo A subtipos H5N2, H7N3 y H5N1.
- 2. La geografía de México lo coloca al centro de varias rutas de aves migratorias hacia el sur del continente en los meses previos al invierno, lo cual lo expone continuamente a brotes de enfermedades transmitidas por aves silvestres.
- 3. Los avicultores han sufrido los efectos de los brotes de influenza aviar, y gracias a los programas de vacunación que se mantienen, los daños en los brotes más recientes no han sido tan dramáticos como en el pasado (1994).
- 4. De acuerdo con los datos del Compendio Estadístico 2023 emitido por la Unión Nacional de Avicultores, el costo de vacunación total representa el rubro con menor impacto en los costos de producción en la avicultura.

De lo anterior, nos permitimos resaltar la importancia de la vacunación contra Influenza Aviar de Alta Patogenicidad H5N1, visto bajo los siguientes ejes:

RECOMENDACIONES DE LA ORGANIZACIÓN MUNDIAL DE SANIDAD ANIMAL (OMSA)

De acuerdo con la información publicada en la página web de la OMSA (<u>https://www.woah.org/es/enfermedad/influenza-aviar/</u>), se refiere a la influenza aviar con estas premisas:

La Influenza aviar implica terribles consecuencias para la industria avícola, los medios de subsistencia de los productores, el comercio internacional y la sanidad de las aves silvestres. La influenza aviar, más conocida como "gripe aviar", acapara la atención de la comunidad internacional desde hace años.

A menudo, cuando se produce un brote, se decide sacrificar a todas las aves de corral, tanto infectadas como sanas, con el fin de contener la propagación de esta enfermedad, lo que supone grandes pérdidas económicas para los productores y un impacto a largo plazo en sus medios de subsistencia.



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Sin embargo, las aves de corral no son las únicas afectadas. Las aves silvestres también son víctimas del virus de la influenza aviar, además de desempeñar un papel importante en la propagación de la enfermedad.

Esta enfermedad es también objeto de gran preocupación para el sector de la salud pública. Si bien el virus de la influenza aviar circula en las aves de corral, se han observado casos esporádicos en los seres humanos.

Siendo así que nos referimos a algunas de las resoluciones emanadas de la Asamblea Mundial celebrada en mayo de 2023 (Resolución No. 28 https://www.woah.org/app/uploads/2023/06/e-resos-2023-all.pdf) sobre la vacunación contra IAAP, de entre las cuales, deseamos resaltar las siguientes:

- La recurrencia global, la propagación y el aumento significativo de infecciones aviares generadas por la Influenza Aviar de Alta Patogenicidad (IAAP), está afectando a las aves domésticas, silvestres, aves terrestres y mamíferos acuáticos, lo que refleja un cambio distintivo en la epidemiología y ecología del virus de la IAAP, el cual supone una amenaza para la sanidad animal, la salud pública, la seguridad alimentaria y la biodiversidad.
- Las medidas de control convencionales de bioseguridad, sacrificio sanitario y restricciones de movilización de mercancías de origen avícola, si bien son útiles para la contención de eventos sanitarios, pueden resultar insuficientes e insostenibles dada la variación global en la producción sistemática, la persistente amenaza de nuevas variantes y la alta carga viral presente en los ambientes debido a las fuentes donde se ubica el virus.
- El impacto de la enfermedad y el sacrificio masivo de aves de corral resultan en pérdidas económicas sustanciales en la producción y las industrias asociadas, generando efectos negativos duraderos en la vida de los avicultores, en sus medios de subsistencia e incluso su salud mental, altos costos para el gobierno y la sociedad y preocupaciones ambientales.

La vacunación con vacunas registradas de alta calidad que sean eficaces contra las cepas de campo en circulación puede proporcionar protección adicional y reducir las cantidades del virus y el riesgo de una mayor propagación. La vacunación requiere la adaptación de la vigilancia para la detección precoz, la demostración de la ausencia de influenza aviar de alta patogenicidad y el seguimiento de los cambios en las cepas en circulación.

De acuerdo con las normas internacionales de la OMSA, **el uso de la vacunación no afectará al estatus de un país o zona libre de influenza aviar de alta patogenicidad si su vigilancia respalda la ausencia de infección.**

En México la vacunación ha demostrado ser una herramienta de alta importancia en el control y erradicación de la Influenza Aviar, lo que ha permitido que la Industria Avícola nacional mantenga una parvada de más de 500 millones de aves y continúe dentro de los 10 primeros lugares de producción de huevo y pollo en el mundo. Esto hace que contar con una estrategia de prevención de enfermedades se convierta en una herramienta crítica para la industria avícola mundial.

Cabe señalar que la localización geográfica de México, lo convierte en un país de paso obligado para la migración de aves silvestres hacia el Sur del continente en los meses previos al invierno, considerándose, por lo tanto, un riesgo latente para la parvada avícola nacional, sin olvidar que en este momento nuestro país es endémico para el virus de influenza aviar H5N2 y H7N3.

Por otro lado, se considera que el riesgo de tener brotes de Influenza Aviar subtipo H5N1 continúa latente dada la prevalencia del virus en las aves migratorias y que resulta cada vez más agresivo, tal como se señaló en sesión reciente del Centers of Excellence for Influenza Research and Response (CEIRR), donde se agregó que en California se vacunaron CONDORES con vacuna comercial de Reversa Genética H5N1.



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La estrategia vacunal tiene un alto valor epidemiológico utilizando vacunas aprobadas por el gobierno de manera preventiva. Hoy en día gracias a la tecnología y a los avances en el diagnóstico oportuno es posible contar con vacunas que permiten diferenciar aves vacunadas de aves infectadas por cepas de campo; herramientas que pueden ser incluidas en el plan de prevención y control de enfermedades siempre bajo la supervisión de las autoridades.

Es de alta relevancia señalar que la vacunación contra la Influenza Aviar, debe de cumplir con 3 objetivos críticos:

1.- Prevenir la enfermedad en las aves vacunadas dándoles resistencia ante un desafío.

2.- Evitar signos clínicos y mortalidad que repercute en las pérdidas para los avicultores, así como en el abasto de proteína para la población.

3.-Reducir la excreción viral lo que conlleva al control de la enfermedad con un medio ambiente libre de enfermedad contribuyendo al bienestar de todos.

Las vacunas de nueva tecnología se están evaluando bajo este contexto.

ENFOQUE DE UNA SALUD.

La FAO promueve la aplicación del enfoque "Una salud" como parte de la transformación del sistema agroalimentario a favor de la salud de las personas, animales, plantas y el medio ambiente. "Una salud" es un enfoque unificador integrado que procura equilibrar y optimizar de manera sostenible la salud de las personas, los animales y los ecosistemas. El enfoque reconoce que la salud de las personas, los animales domésticos y salvajes, las plantas y el medio ambiente en general (incluidos los ecosistemas) están estrechamente relacionados y son interdependientes. (Definición de "Una salud" elaborada por el OHHLEP, 2021); la adopción del enfoque "Una salud" resulta también fundamental para la consecución de los Objetivos de Desarrollo Sostenible (ODS).

Dicho enfoque cobra relevancia en este tema considerando que con base en el Informe técnico: *Virus A(H5N1) de la influenza aviar altamente patógena*, emitido por los Centros para el Control y la Prevención de Enfermedades (CDC), actualizado el 7 de julio del 2023 (anexo), se debe tomar en cuenta que:

- Considerando la alta prevalencia de los virus A(H5N1) de la forma altamente patógena de la influenza aviar en aves silvestres y de corral en todo el mundo, se prevé la transmisión viral a mamíferos (particularmente, carnívoros que se alimentan de especies aviares infectadas) y otras infecciones zoonóticas esporádicas entre personas con exposición a aves de corral y silvestres enfermas o muertas.
- Si bien la evaluación de los CDC (anexo) señala que la amenaza general para la salud pública de los virus A(H5N1) del clado 2.3.4.4b es baja por el momento, la prevalencia de propagación geográfica en aves de corral y aves infectadas eleva la posibilidad de exposiciones a seres humanos y otros mamíferos.

Adicionalmente, de acuerdo con la *"Actualización semanal de la influenza aviar número 907"* publicado por la Organización Mundial de la Salud, el 4 de agosto de 2023, titulado *"Infección humana por virus de la influenza aviar A(H5)"*, entre el 28 de julio y el 3 de agosto de 2023, no se reportaron nuevos casos de infección humana por virus de la Influenza Aviar A(H5N1) en la Región del Pacífico Occidental. No obstante, hasta el 3 de agosto de 2023, se habían registrado un total de 244 casos de infección humana por virus de la gripe aviar A(H5N1) notificados en cuatro países de la región del Pacífico occidental desde enero de 2003.

De estos casos, 136 fueron mortales lo que resultó en una tasa de letalidad (CFR) del 56%, mientras que la tasa de letalidad de la pandemia causada por el SARS-CoV-2 virus/COVID-19 es de aproximadamente 2%-3% en todo el mundo.



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Es de vital importancia resaltar que los contagios detectados **NO SE VINCULAN AL CONSUMO DE LA PROTEÍNA ANIMAL** sino al contacto directo con las aves afectadas.

En ese sentido, esta Industria Farmacéutica Veterinaria solicita respetuosamente, **considerar un Análisis de Impacto Regulatorio del Acuerdo en comento**, en el que se incorpore el impacto que las disposiciones que deriven del mismo pudieran tener en la salud humana.

PREVENCIÓN Y CONTROL INTEGRAL DE LA ENFERMEDAD

Limitar la propagación de la Influenza Aviar de alta patogenicidad es una prioridad para los países productores de aves de corral en todo el mundo. Sin cura disponible para dicha enfermedad, los países utilizan una combinación de tácticas de prevención que mejor protegen a sus aves locales y al sector avícola (sacrificio, bioseguridad, vigilancia, biológicos) adaptadas a su situación.

Este sector altamente relacionado con la sanidad animal reconoce la importancia del control integral de la Influenza Aviar altamente patógena para los productores avícolas. Muchas empresas están desarrollando nuevas tecnologías que pueden mejorar la capacidad de los países para prevenir y limitar la propagación de la gripe aviar altamente patógena y ayudar a garantizar la continua libre circulación del comercio, esto incluye nuevas vacunas, diagnósticos, monitoreo digital y otras herramientas emergentes.

Dentro de un esquema de prevención y control integral de la IA H5N1, es importante considerar a la vacunación como una herramienta necesaria y diseñar un plan de acción que promueva que todos los actores involucrados en la cadena productiva de la proteína avícola estén preparados para atender la enfermedad. En este punto es importante resaltar que, de declarar al país libre de Influenza Aviar H5N1 y presentarse un brote de esta, el tiempo de respuesta de la Industria Farmacéutica Veterinaria para proveer biológicos de calidad para su atención, sería como mínimo de tres meses.

En ese sentido el sector de la salud animal está listo para trabajar con los productores avícolas y las autoridades en la definición de la combinación adecuada de herramientas para contar con una estrategia nacional de prevención, y seguir desempeñando un papel fundamental en la respuesta a la Influenza Aviar altamente patógena.

INEXISTENCIA DE CONDICIONES PARA OPERER UN FONDO NACIONAL DE ASEGURAMIENTO EN AVICULTURA EN LA ACTUALIDAD.

La Influenza Aviar altamente patógena (IAAP) representa una amenaza sin precedentes para las aves de corral y otras especies aviares en todo el mundo. Más de 500 millones de aves han sucumbido o han sido sacrificadas desde 2005, según la Organización Mundial de Sanidad Animal (WOAH), y este número puede seguir aumentando.

La Influenza Aviar altamente patógena es un problema crítico para los clientes de las empresas de salud animal y la cadena de valor alimentaria en general, ya que un suministro constante de proteína de origen avícola es esencial para proveer de alimentos asequibles a la población mexicana.

En ese sentido, cobra relevancia la carencia de condiciones para operar un Fondo de Aseguramiento Avícola, en virtud de que **las empresas de reaseguro existentes en el mercado mexicano o bien no suscriben programas para ganadería de ningún tipo y quienes si lo hacen (los menos) no suscriben riesgos relacionados con enfermedades exóticas**, en general las coberturas que ofrecen estas compañías son por accidentes (derivadas de eventos de la naturaleza como huracanes, incendio y otros).

La principal razón es que consideran que la exposición actual a la influenza aviar es muy alta en México tomando en cuenta los brotes de los últimos años y esto les genera una muy elevada incertidumbre.



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Adicionalmente, en los últimos años prevalece una reducción de la capacidad de reaseguro en la región de Latinoamérica para negocios agrícolas/ganaderos derivados de las grandes pérdidas de 2021/2022 que se tuvieron en la región de Latinoamérica principalmente en el sur del continente (Brasil, Argentina y Paraguay) con motivo de una sequía prolongada sin precedentes que detonó en pérdidas para los mercados de reaseguro, por lo cual los mercados y la capacidad en la región se ha visto reducidos.

En virtud de lo anterior, la vacunación juega un papel fundamental, al no existir las condiciones adecuadas en cuanto a seguros para que los productores afronten el impacto de un brote de Influenza Aviar Tipo A Subtipo H5N1 en sus granjas, que conlleve el sacrificio de las aves.

MEJORA REGULATORIA. RELACIÓN COSTO-BENEFICIO DE LAS REGULACIONES.

En este punto se debe considerar que conforme a los artículos 67 y 68 de la Ley General de Mejora Regulatoria que da fundamento a esa Comisión Nacional de Mejora Regulatoria, los Análisis de Impacto Regulatorio deben contribuir a que las Regulaciones se diseñen sobre bases económicas, empíricas y del comportamiento, sustentadas en la mejor información disponible, así como promover la selección de alternativas regulatorias cuyos beneficios justifiquen los costos que imponen y que generen el máximo beneficio para la sociedad, por lo que al presentar una exención de AIR para el documento en comento, no se consideran los costos o impactos asociados a la regulación.

Como parte de ese máximo beneficio para la sociedad que se señala en el párrafo anterior, es importante considerar que como parte de la Visión 2024 considerada en el Plan Nacional de Desarrollo de la actual administración pública federal, se prevé que para 2024 deberá cumplirse la meta de alcanzar la autosuficiencia en carne de ave y huevo; no obstante, al día de hoy nuestro país produce alrededor del 85% de la carne de pollo que se demanda, por lo que cualquier política o regulación que ponga en riesgo a la producción avícola nacional, resulta contraria a este propósito de autosuficiencia.

Por todo lo antes expuesto y en apego a las consideraciones de la OMSA esta Industria Farmacéutica Veterinaria en apoyo a la Industria Avícola Nacional considera conveniente **mantener la vacunación como MEDIDA PREVENTIVA contra la Influenza Aviar Altamente Patógena H5N1** en las regiones en que exista el riesgo de tener nuevos brotes de la enfermedad o introducción de nuevas variantes, sin menoscabo del continuo fortalecimiento de las buenas prácticas pecuarias y las medidas de bioseguridad; lo cual además abonará a reducir el riesgo de que esto pueda convertirse en una enfermedad zoonótica y redundará en beneficios sanitarios y económicos para el país.

Sin más por el momento, agradezco su atención.

entamente **Rocío Reves Pérez Jiménez**

Mtra Rocio Reyes Perez Jimenez Directora Ejecutiva INDUSTRIA FARMACÉUTICA VETERINARIA DE LA CÁMARA NACIONAL DE LA INDUSTRIA FARMACÉUTICA



Centros para el Control y la Prevención de Enfermedades CDC 24/7: Salvamos vidas, Protegemos a la gente™

Influenza (gripe)

Influenza (gripe) Inicio



Informe técnico: Virus de la influenza aviar A (H5N1) altamente patógena

Actualizado el 7 de julio del 2023

Este informe es una actualización del informe original publicado el 17 de marzo del 2023, e incluye información sobre otros casos esporádicos en seres humanos y actividad entre aves silvestres, de corral y otros animales. El riesgo general para la salud humana asociado a los brotes en curso de virus A(H5N1) altamente patógenos en aves silvestres y aves de corral no ha cambiado y permanece bajo en este momento.

Resumen ejecutivo

A pesar de la naturaleza panzoótica de los virus de la influenza aviar A(H5N1) altamente patógena (HPAI) en aves silvestres y aves de corral, desde el 2022 solo se ha identificado una cantidad mínima de casos esporádicos del virus de influenza A(H5N1) en seres humanos. Prácticamente todos los casos en seres humanos notificados desde el 2022 estuvieron asociados a exposiciones recientes a aves de corral, y no se han identificado casos de contagio entre personas o de mamíferos a personas del virus A(H5N1) de la HPAI. En algunos casos se desconoce la fuente de exposición al virus A(H5N1) de la HPAI. A la fecha, los virus A(H5N1) HPAI en circulación en aves y aves de corral con derrame a mamíferos, y aquellos que han causado infecciones en seres humanos, no tienen la capacidad de fijarse fácilmente a los receptores que predominan en las vías respiratorias superiores de los seres humanos. Por consiguiente, el riesgo actual para el público de los virus A(H5N1) de la forma altamente patógena de la influenza aviar sigue siendo bajo. Sin embargo, debido a la prevalencia global de brotes de los virus A(H5N1) de la forma altamente patógena de la influenza aviar en brotes en aves silvestres y aves de corral, se anticipa que continúen los casos esporádicos de infecciones en humanos. Si bien los brotes en las bandadas de aves en los EE. UU. han disminuido considerablemente durante los meses de primavera y verano, la circulación a nivel mundial en curso de los virus A(H5N1) de la HPAI en aves silvestres, y su capacidad para propagarse a lo largo de las rutas migratorias y evolucionar rápidamente justifican una vigilancia exhaustiva de estos virus en aves silvestres, aves de corral, mamíferos y personas en todo el mundo, y las reevaluaciones frecuentes para determinar el riesgo para la salud pública, junto con esfuerzos de preparación constantes.

Puntos clave

- Los CDC están trabajando activamente en las situaciones en el país que involucran virus A(H5N1) de la HPAI del clado 2.3.4.4b asociadas a infecciones en brotes en aves silvestres y aves de corral, lo que incluye la vigilancia entre las personas con exposiciones relevantes y la preparación ante la posibilidad de que los virus A(H5N1) de la HPAI desarrollen la capacidad de mayor transmisibilidad a las personas.
- Los CDC, junto con sus socios de salud pública estatales y locales, siguen monitoreando activamente a las personas en los Estados Unidos que estuvieron expuestas a aves de corral y aves infectadas por 10 días después de la exposición. A la fecha, se ha monitoreado a más de 6 500 personas en 52 jurisdicciones desde el 2022, y solo se ha identificado un caso en seres humanos.
- Ya está disponible un virus H5 de vacuna experimental (CVV, por sus siglas en inglés) producido por los CDC que se espera que ofrezca buena protección contra los virus A(H5N1) de la HPAI del clado 2.3.4.4b detectados en aves y mamíferos, y ha sido compartido con los fabricantes de vacunas.
- Como los virus de la influenza cambian constantemente, los CDC realizan análisis constantes de los virus A(H5N1) de la HPAI para identificar cambios que podrían propiciar una propagación más fácil entre las personas, causar una enfermedad grave en las personas, reducir la susceptibilidad a los antivirales, afectar la sensibilidad de las pruebas de diagnóstico o reducir el efecto de neutralización de los virus por parte de los anticuerpos inducidos por vacunas. A la fecha se han identificado pocos cambios en los virus A(H5N1) de la HPAI que sean de preocupación para la salud pública, y dichos cambios han variado entre los diversos virus A(H5N1) de la HPAI que circulan en aves silvestres y aves de corral de todo el mundo o que han provocado infecciones esporádicas en seres humanos. No se han identificado cambios en los virus actuales A(H5N1) de la HPAI del clado 2.3.4.4b en aves silvestres, aves de corral, mamíferos o casos en seres humanos que sugieran una mayor transmisibilidad a los humanos.

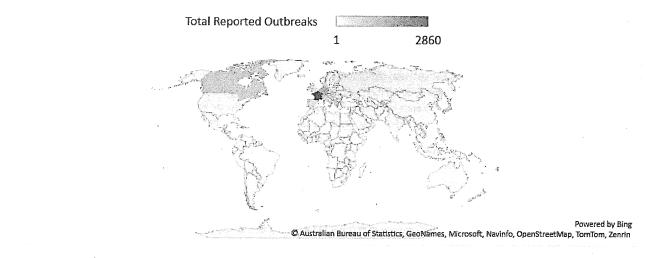
- En la actualidad, se cree que los virus A(H5N1) de la HPAI que circulan entre las aves representan un riesgo bajo para la salud del público en general en los Estados Unidos; sin embargo, las personas con exposición a aves infectadas relacionada con su trabajo o con actividades recreativas podrían tener mayor riesgo de infección y deberían adoptar las precauciones correspondientes que se describen en las guías de los CDC.
- La vigilancia integral y las iniciativas de preparación siguen su curso y los CDC adoptan constantemente medidas de preparación en caso de riesgo para las personas a causa de cambios en los virus A(H5N1) HPAI u otros virus nuevos de la influenza A.

Virus A(H5N1) de la forma altamente patógena de la influenza aviar en aves silvestres y de corral

Desde el 2005, los virus A(H5N1) de la forma altamente patógena de la influenza aviar han atravesado procesos amplios de diversificación genética que incluyeron la formación de cientos de genotipos posteriores a su reagrupación con otros virus A de la influenza aviar. Los virus A(H5N1) del clado 2.3.4.4b de la forma altamente patógena de la influenza aviar aparecieron en el 2020 y llegaron a Norteamérica a fines del 2021 [1,2] para luego propagarse a América Central y Sudamérica, lo que resultó en brotes en aves silvestres y de corral en muchos países [3–5].

Estos virus A(H5N1) del clado 2.3.4.4b de la forma altamente patógena de la influenza aviar se han propagado en todo el mundo causando cantidades récord de brotes en aves silvestres, domésticas, locales y de corral. 77 estados miembro han notificado más de 15 600 brotes en animales por los virus A(H5N1) de la forma altamente patógena de la influenza aviar a la World Organisation for Animal Health 🖸 desde enero del 2022.

Reported HPAI A(H5N1) Animal Outbreaks* Reported to the World Organisation for Animal Health (WOAH), Jan 2022-Jun 2023



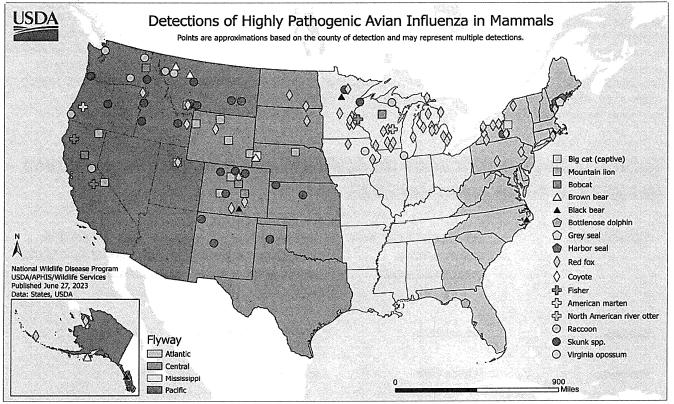
* La WOAH define un brote como la aparición de uno o más casos en un grupo de animales con una relación epidemiológica definida. Por consiguiente, la cantidad de brotes no refleja la cantidad de animales afectados.

En los Estados Unidos, el APHIS del USDA monitorea la aparición de virus de la influenza aviar 🖆 en aves silvestres, de cría comercial y de corral. Desde enero del 2022 hasta el 27 de junio del 2023, el APHIS notificó detecciones del virus A(H5)/A(H5N1) de la HPAI en más de 7,000 aves silvestres 🖆 en 50 estados o territorios, y más de 800 bandadas de cría comercial y de corral 🗹 en 47 estados o territorios. No se han detectado virus A(H5)/A(H5N1) de la HPAI en aves de corral domésticas ni comerciales en los EE. UU. desde el 19 de abril del 2023 y el 18 de mayo del 2023, respectivamente, lo que representa una disminución en comparación con el mismo periodo del 2022.

Infecciones por los virus A(H5N1) de la forma altamente patógena de la influenza aviar entre mamíferos

Se han notificado infecciones esporádicas por el virus A(H5N1) de la HPAI (forma altamente patógena de la influenza aviar) en mamíferos desde el 2003 durante los brotes del virus A(H5N1) de la HPAI en aves de corral o aves silvestres. [6–8]. Se sabe que los virus A(H5) de la HPAI infectan en ocasiones a mamíferos que comen aves o aves de corral (presumiblemente infectadas) o a mamíferos expuestos a entornos con alta concentración del virus.

En los Estados Unidos, entre mayo del 2022 y el 27 de junio del 2023, el APHIS del USDA notificó 🖸 la detección del virus A(H5N1) de la HPAI en 196 mamíferos de diferentes especies en 26 estados o territorios. En el mundo se han notificado infecciones por el virus A(H5N1) de la HPAI en diversas especies de mamíferos en varios países; por ejemplo, en visones de granja en España 🖸 , focas grises y de puerto en los Estados Unidos, lobos marinos de Perú y Chile 🖸 , un gato en Francia y otros países, y zorros en Norteamérica y Europa [9]. Los informes de infecciones por el virus A(H5N1) de la HPAI en mamíferos no sorprenden dados los brotes generalizados de infecciones por el virus A(H5N1) de la HPAI en aves silvestres.



Fuente: APHIS del USDA | Detección de la forma altamente patógena de la influenza aviar en mamíferos en 2022-2023

🔀 Ampliar

Los datos genéticos han revelado que cuando algunos mamíferos se infectan por el virus A(H5N1) de la forma altamente patógena de la influenza aviar, el virus puede atravesar un proceso de evolución en su huésped, lo que resulta en cambios genéticos que le permiten al virus replicarse de manera más eficiente en las vías respiratorias inferiores [10-12].

Aunque estos cambios genéticos pueden impactar en las consecuencias de la enfermedad para los mamíferos, no han sido asociados a una especificidad de unión a receptor o a una mayor transmisibilidad del virus a los seres humanos. En la actualidad, los virus A(H5N1) de la forma altamente patógena de la influenza aviar no tienen la capacidad de infectar fácilmente y fijarse a los receptores del ácido siálico en el enlace α 2,6, que son los que predominan en las vías respiratorias superiores de los seres humanos [2], lo que sería necesario para aumentar el riesgo de transmisión a las personas [13,14].

Casos de A(H5N1) en seres humanos

Si bien los virus A(H5N1) de la forma altamente patógena de la influenza aviar están en circulación extendida entre aves silvestres y de corral en muchas regiones geográficas, en los últimos años se ha a notificado una cantidad relativamente baja de casos de A(H5N1) en seres humanos [figura 1]. Desde enero del 2022 hasta el 29 de junio del 2023, se notificaron trece casos esporádicos del virus A(H5N1) en seres humanos de ocho países, incluidos seis casos graves y dos muertes, dos casos leves y cinco casos asintomáticos. [Tabla 1].

En los Estados Unidos se notificó un caso de A(H5N1) en un ser humano en abril del 2022. La persona refirió fatiga sin otros síntomas y se detectaron niveles bajos de ARN viral para A(H5N1) en una sola muestra de las vías respiratorias superiores. Es posible que la detección de ARN viral para A(H5N1) resultara de la deposición de material viral no infeccioso en las vías respiratorias superiores de la persona y no representara una infección real, similar a la contaminación ambiental atribuida a los dos casos asintomáticos notificados en trabajadores de una granja de aves de corral en España [15] y además podría explicar la detección del ARN del virus A(H5N1) en otros trabajadores avícolas asintomáticos en el Reino Unido. [16].

Casi todos los casos en seres humanos de infección por el virus A(H5N1) notificados desde el 2022 tenían antecedentes recientes de exposición a aves de corral enfermas o muertas, y no se identificó ningún caso de transmisión del virus A(H5N1) de la HPAI entre personas. Seis casos (3 niños, 3 adultos) se enfermaron gravemente y dos murieron. Diez casos estuvieron asociados a virus A(H5N1) de la HPAI el clado 2.3.4.4b, la HA del clado en un caso en Vietnam no pudo determinarse y dos casos en Camboya estuvieron asociados al clado 2.3.2.1c de los virus A(H5N1) de la HPAI; ninguna de las secuencias genéticas de estos virus A(H5N1) de la HPAI contenía marcadores conocidos de menor susceptibilidad a los medicamentos antivirales para la influenza actualmente recomendados y aprobados por la FDA.

Tabla 1. Casos notificados de A(H5N1) en seres humanos, enero del 2022 al 29 de junio del 2023

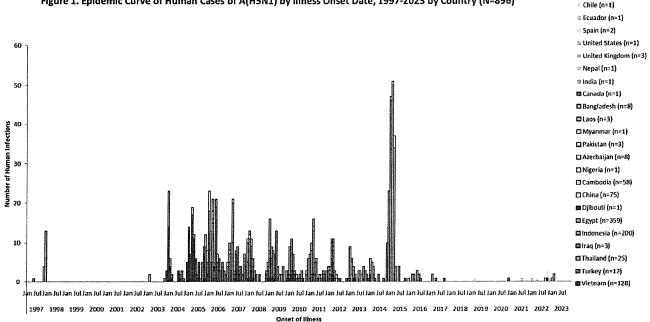
País del caso	Mes de aparición de la enfermedad o detección del caso	Gravedad y consecuencias de la enfermedad	Clado del virus por secuenciación o brotes en aves de corral asociados
Camboya	Febrero 2023	Enfermedad grave, murió	Clado 2.3.2.1c
Camboya	Febrero 2023	Enfermedad leve, sobrevivió	Clado 2.3.2.1c
Chile*	Marzo 2023	Enfermedad crítica	Clado 2.3.4.4b
China	Septiembre 2022	Enfermedad grave, murió	Clado 2.3.4.4b
China	Enero 2023	Hospitalización, no se notificó resultado final	Clado 2.3.4.4b
Ecuador	Diciembre 2022	Enfermedad grave, sobrevivió	Clado 2.3.4.4b
España	Septiembre 2022	Asintomático	Clado 2.3.4.4b
España	Octubre 2022	Asintomático	Clado 2.3.4.4b
Reino Unido	Enero 2022	Asintomático	Clado 2.3.4.4b

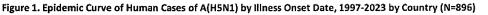
Reino Unido	Мауо 2023	Asintomático	Clado 2.3.4.4b
Reino Unido	Мауо 2023	Asintomático	Clado 2.3.4.4b
Estados Unidos	Abril 2022	Solo fatiga, sobrevivió	Clado 2.3.4.4b
Vietnam	Octubre 2022	Enfermedad grave, sobrevivió	No informado

*Hay más detalles sobre el caso/paciente de Chile y las características del virus en: /flu/avianflu/spotlights/2022-2023/chile-first-caseh5n1-addendum.htm

Desde 1997, se ha notificado un total de 896 infecciones esporádicas en seres humanos por el virus A(H5N1) en 22 países [figura 1], causados por diferentes clados del virus A(H5N1) de la forma altamente patógena de la influenza aviar [17], con una proporción de muerte acumulada superior al 50 %. La incidencia anual de casos de infección por el virus A(H5N1) en humanos ha sido mayor en el 2015 (145 casos, 4 países) principalmente debido a una gran epidemia en Egipto con 136 casos, seguidos por el 2006 (115 casos, 9 países) [figura 1].

Casi todos los casos de A(H5N1) en seres humanos notificados estaban asociados a exposiciones a aves de corral enfermas o muertas o a visitas a mercados de aves vivas. Es probable que se hayan producido algunas transmisiones entre personas poco frecuentes, limitadas y no sostenidas del virus de la influenza A(H5N1) de la HPAI en una cantidad reducida de familiares después de la exposición prolongada, estrecha y sin protección con un paciente sintomático durante el 2004-2007 en varios países [18-21].





🔀 Ampliar

Monitoreo activo de personas expuestas al virus A(H5N1) de la forma altamente patógena de la influenza aviar en los Estados Unidos

Si bien en el último tiempo hubo algunos casos en seres humanos, dada la extensión de las infecciones entre aves de corral y aves silvestres, las personas con exposición por motivos laborales o recreativos a aves infectadas o a mamíferos enfermos o muertos podrían correr mayor riesgo de infección.

Los CDC, junto con socios de salud pública estatales, territoriales y locales, monitorean de manera activa a las personas expuestas (p. ej., propietarios de bandadas, trabajadores agrícolas y mataderos) a aves de corral comerciales, aves domésticas, aves silvestres y a ambientes con aves infectadas por el virus A(H5N1) de la HPAI durante 10 días después de la última exposición [22]. Al 29 de junio del 2023:

- Total de personas monitoreadas: más de 6 500 en 52 jurisdicciones desde febrero del 2022
- Cantidad total de casos con pruebas de influenza notificadas entre las personas monitoreadas: más de 160 personas
- Cantidad de resultados positivos para el virus de la influenza A(H5N1): 1

De las aproximadamente 160 personas con síntomas a quienes se les realizaron pruebas de detección de virus de la influenza estacional A nuevos, además de otros virus respiratorios, se detectó material genético del virus A(H5N1) de la influenza aviar altamente patógena en una persona de Colorado que refirió fatiga sin ningún otro síntoma al sacrificar aves de corral. [Ver la sección de arriba sobre "Casos de A(H5N1) en seres humanos."]

Vigilancia de la influenza en los EE. UU. para detectar infecciones en seres humanos con virus nuevos de la influenza A, incluido el virus A(H5N1) de la forma altamente patógena de la influenza aviar

La infección en seres humanos por un virus nuevo de la influenza A, incluido el virus A(H5N1) de la influenza aviar altamente patógena, es una afección de notificación obligatoria a nivel nacional (definición de caso: Definición de caso de infecciones por un virus A de la influenza nuevo, 2014 | CDC).

Hay pruebas de detección de la influenza ampliamente disponibles en laboratorios clínicos y centros de atención médica. Las pruebas en estos entornos permiten detectar infecciones por el virus de la influenza A(H5N1) como positivas para influenza A, y hay un subgrupo de pruebas que también permitirían determinar que no se trata de los subtipos de virus de influenza A (H1 o H3) que suelen circular entre los seres humanos. Las pruebas de personas que pudieron haber estado expuestas al virus H5N1 o que dan positivo para un virus de influenza A pero negativo para los subtipos A(H1) y A(H3) se deben enviar al laboratorio de salud pública estatal o local para un análisis más exhaustivo. Se han enviado muy pocas muestras a los CDC para la realización de pruebas de detección del H5 desde enero del 2022.

- Las pruebas de detección del virus de la influenza estacional que también permiten detectar virus nuevos de influenza A se usan en 128 laboratorios de salud pública de los 50 estados de los EE. UU.
- Hay pruebas de diagnóstico específicas para detectar virus A(H5) actuales en 99 laboratorios de salud pública de los 50 estados.

De conformidad con protocolos estándar de larga data, al detectar un virus positivo para la influenza A, pero negativo para los genes H1 o H3 del virus de influenza humana, el laboratorio de salud pública contactará inmediatamente a los CDC y les enviará la muestra. Las muestras que son positivas para la influenza A pero negativas para los genes H1 o H3 humanos también pueden ser analizadas para H5 por los laboratorios de salud pública estatales y se envían rápidamente a los CDC para obtener un resultado de diagnóstico. Se inicia una investigación del caso y se completa un formulario de notificación de caso que se envía a los CDC a través del módulo de notificación de virus de influenza A nuevos.

Actividades de preparación de los CDC y el gobierno de los EE. UU.

Actividad

Resumen

Vigilancia mundial y respuesta rápida a infecciones en humanos	La División de Influenza de los CDC brinda apoyo a la vigilancia en mercados de aves vivas, granjas domésticas y aves silvestres y/o sus entornos en Bangladesh, Camboya, China, Guatemala, Kenia, Laos, Perú, Tailandia y Vietnam. Los datos de vigilancia señalan la alta prevalencia y amplia variedad de virus A de la influenza aviar en aves y ayudan a describir los cambios en la epidemiología de los virus A de la influenza aviar. En 2022, la División de Influenza hizo el seguimiento de más de 50 infecciones en seres humanos con los virus A de la influenza aviar notificadas a la OMS por parte de siete países en cuatro regiones de la OMS. En el último tiempo, el personal de campo de la División de Influenza de los CDC colaboró en investigaciones de respuesta rápida de dos casos de H5N1 en seres humanos en Camboya en el 2023
Evaluaciones virológicas	Como los virus de la influenza tienen altos índices de error durante su replicación y evolucionan rápidamente, los CDC realizan análisis genéticos de manera constante a los virus para identificar cambios que puedan impactar en sus fenotipos, como su antigenicidad, susceptibilidad a los antivirales, transmisibilidad y/o patogénesis. También se analizan genéticamente para evaluar cambios que puedan afectar el rendimiento de las pruebas de diagnóstico.
Diagnóstico	Hay diferentes pruebas de diagnóstico de reacción de la cadena de polimerasa en transcripción reversa (RT-PCR, por sus siglas en inglés) en tiempo real de virus de la influenza de los CDC permiten detectar los virus típicos (estacionales) que afectan a los seres humanos o virus nuevos de influenza A (por ejemplo, H5, H7) que pueden infectar a personas por transmisión zoonótica. Estas pruebas de diagnóstico se utilizan en los 50 estados de los EE. UU. y en todo el mundo. Además, existen pruebas de diagnóstico de los CDC que detectan específicamente los virus H5 actuales, las cuales están disponibles en los laboratorios de salud pública en los 50 estados de los EE. UU. y en laboratorios internacionales. Es probable que la mayoría de las pruebas comerciales utilizadas para la detección de virus de la influenza en seres humanos permitan detectar los virus A(H5N1) de la forma altamente patógena de la influenza aviar porque apuntan a las proteínas conservadas.
Desarrollo de virus de vacuna experimental	El desarrollo de virus de vacuna experimentales (CVV), en coordinación con la OMS, sigue siendo un componente esencial de la estrategia global de preparación para una pandemia de influenza. Se ha creado una biblioteca de virus H5 de vacuna experimental con recomendaciones adicionales para su desarrollo durante las reuniones de consulta bianuales sobre vacunas (Vea la Tabla y https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/zoonotic-influenza-viruses-and-candidate-vaccine-viruses I). La herramienta de evaluación del riesgo de influenza de los CDC también se utiliza para ayudar a priorizar los virus A(H5) de la HPAI para el desarrollo de virus de vacuna experimental.
	relacionados con los virus H5N1 de la HPAI (clado 2.3.4.4b) en circulación en América del Norte y están a disposición de los fabricantes de vacunas. Los dos virus A(H5) de vacuna experimental producidos por los CDC (es decir, IDCDC-RG71A) y la FDA (CBER-RG8A) de los EE. UU. codifican una hemaglutinina (HA) que es casi idéntica a la HA de los virus A(H5N1) del clado 2.3.4.4b más recientes detectados en aves, mamíferos silvestres y seres humanos, y podrían usarse para producir una vacuna para las personas, si fuera necesario. Se ha recomendado el desarrollo de dos virus A(H5N1) del clado 2.3.4.4b de vacuna experimental como parte de la preparación para la pandemia para ampliar el rango de protección contra los virus A(H5N1) de la HPAI a nivel mundial que puedan variar antigénicamente de los CVV actualmente disponibles.

Las cepas de virus de influenza A cambian con el tiempo y hay varias cepas que circulan entre los animales todos los años y pueden ocurrir algunas infecciones por el nuevo virus de influenza A en seres humanos sin que esto provoque un contagio sostenido entre personas. El gobierno de los EE. UU. tiene un programa de preparación que permite una respuesta rápida a las cepas del virus de influenza A a medida que las cepas evolucionan. Como parte de este programa, la Autoridad de Investigación y Desarrollo Biomédico de Avanzada (BARDA) trabaja junto a socios de la industria privada para elaborar y analizar pequeñas cantidades de virus de influenza A con potencial pandémico a medida que aparecen, por si alguno de ellos resulta en contagio sostenido entre personas y al mismo tiempo, sustentar la capacidad de fabricación para propiciar una producción de vacunas contra la influenza a mayor escala cuando sea necesario.

Limitaciones del informe

Este informe está sujeto a las siguientes limitaciones. Primero, la cantidad de infecciones en seres humanos por el virus A(H5N1) clado 2.3.4.4b de la influenza aviar altamente patógena es muy reducida. Las conclusiones de los análisis de caracterización de los virus, su transmisibilidad de animales a personas, transmisibilidad entre personas y espectro de presentación clínica de la enfermedad en personas se deben interpretar considerando esta cantidad pequeña. Segundo, no había información detallada de exposiciones disponible para todas las personas monitoreadas en busca de enfermedad después de la exposición a aves y aves de corral infectadas por el virus A(H5N1) de la forma altamente patógena de la influenza aviar en los Estados Unidos. Por consiguiente, no pudimos evaluar el impacto de las variables de exposición como su duración, naturaleza (por ejemplo, contacto directo o indirecto) y el uso de equipos de protección personal sobre el riesgo de infección.

Conclusiones

- A la fecha, los análisis de los virus A(H5N1) de la HPAI del clado 2.3.4.4b realizados por los CDC en aves silvestres, aves de corral y esporádicamente en mamíferos desde fines del 2021 indican que todos estos virus tienen un alto grado de identidad genética entre sí y no se identificó ninguna sustitución adaptativa, inserción ni eliminación en mamíferos significativa, particularmente en el gen de la HA, que es importante para la transmisión zoonótica y el posterior contagio entre personas.
- Considerando la prevalencia alta de los virus A(H5N1) de la forma altamente patógena de la influenza aviar en aves silvestres y
 de corral en todo el mundo, se prevé el derrame a mamíferos (particularmente, carnívoros que se alimentan de especies aviares
 infectadas) y otras infecciones zoonóticas esporádicas entre personas con exposición a aves de corral y silvestres enfermas o
 muertas.
- La HA de los virus A(H5N1) del clado 2.3.4.4b en circulación en la actualidad en aves silvestres y de corral de todo el mundo no tiene la capacidad de fijarse preferencialmente a los tipos de receptores de ácido siálico que predominan en las vías respiratorias superiores de los seres humanos y, por consiguiente, por el momento no tienen la capacidad de infectar o transmitirse fácilmente entre personas.
- A pesar de la propagación mundial de los virus A(H5N1) de la influenza en aves silvestres y aves de corral en los últimos años, se notificó solo una pequeña cantidad de infecciones en humanos por los virus H5N1 de los clados 2.3.4.4b o 2.3.2.1c desde el 2022; todos los casos tenían exposición reciente a aves de corral y no se identificó ningún caso de transmisión del virus A(H5N1) de la influenza entre personas.

Si bien la evaluación de los CDC es que la amenaza general de la HA de los virus A(H5N1) del clado 2.3.4.4b para la salud pública es baja por el momento, la prevalencia de propagación geográfica en aves de corral y aves infectadas eleva la posibilidad de exposiciones de seres humanos y otros mamíferos, lo que podría provocar la evolución del virus y su redistribución y, a su vez, producir un cambio en la evaluación del riesgo actual. Aunque las detecciones de virus en aves de corral comerciales y aves domésticas en los Estados Unidos disminuyeron considerablemente en los últimos meses, la situación podría cambiar en cualquier momento. La vigilancia en curso de los virus A(H5N1) de la forma altamente patógena de la influenza aviar en circulación en aves silvestres, aves de corral e infecciones esporádicas en mamíferos y personas en todo el mundo es crítica para monitorear el riesgo para la salud pública y detectar cambios genéticos (particularmente, en el gen de la HA) que pudieran modificar la evaluación de riesgo de los CDC.

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Recursos

Definiciones de caso para investigaciones de infección en seres humanos por los virus A de la influenza aviar en los Estados Unidos

Directrices provisionales para la quimioprofilaxis antiviral de influenza en personas expuestas a aves con los virus de influenza aviar A asociados a enfermedades graves en humanos o con el potencial para causar enfermedades graves en humanos

Guía interina sobre el seguimiento de contactos cercanos de personas infectadas por los virus de la nueva influenza A y el uso de medicamentos antivirales como quimioprofilaxis

Breve resumen para médicos: Evaluar y controlar a pacientes expuestos a aves infectadas por los virus de la influenza aviar A que implican una preocupación para la salud pública

Guía interina para la realización de pruebas y recolección de muestras de pacientes con presunta infección por los virus de la nueva influenza A con el potencial de causar enfermedades graves en seres humanos

Guía interina para el control de infecciones en el ámbito del cuidado de salud al atender a pacientes con infección por el virus de la nueva influenza tipo A, confirmada o probable, y a pacientes en investigación, cuando la infección está asociada a un estado grave de la enfermedad | Influenza aviar (gripe aviar) (cdc.gov)

Directrices provisionales para el uso de medicamentos antivirales en el tratamiento de infecciones en seres humanos con los virus nuevos de la influenza tipo A asociados a enfermedades graves

Información adicional

Resumen de situación actual de la influenza aviar | Influenza aviar (gripe aviar) (cdc.gov)

Infecciones por el nuevo virus de influenza A (cdc.gov): panel interactivo de todas las infecciones por el nuevo virus de influenza A en seres humanos notificadas en los Estados Unidos desde el 2010

Infecciones notificadas en humanos por virus de la influenza aviar A

Ejemplos anteriores de probables casos de propagación de persona a persona limitada, no sostenida, de los virus A de la influenza aviar

Aspectos destacados de la cronología de la historia de la influenza aviar - 2020 a 2023

Información para personas expuestas a aves infectadas por los virus de la influenza aviar

Prevención y tratamiento con antivirales de infecciones por el virus de la influenza aviar en personas

Recomendaciones para la protección de los trabajadores y el uso del equipo de protección personal (EPP) para disminuir la exposición a los nuevos virus de la influenza aviar tipo A asociados a enfermedades graves en los seres humanos

Asesoría de salud de los CDC, 29 de abril del 2022 - Virus de la influenza aviar A(H5N1) altamente patógena: Recomendaciones para investigaciones de salud humana y respuesta

Plan de monitoreo de salud pública para grupos de respuesta del USDA/APHIS para la detección del virus de la influenza aviar en aves de corral 📓 [353 KB, 18 páginas] 🖸

Las referencias a los sitios no pertenecientes a los CDC se ofrecen como servicio y no constituyen ni implican el respaldo de estas organizaciones o de sus programas por parte de los CDC o el Departamento de Salud y Servicios Humanos de los EE. UU. Los CDC no son responsables por el contenido de las páginas de estos sitios. Las direcciones URL mencionadas estaban actualizadas a la fecha de publicación.

Última revisión: 7 de julio del 2023



4 August 2023

Human infection with avian influenza A(H5) viruses

Human infection with avian influenza A(H5N1) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H5N1) virus were reported to WHO in the Western Pacific Region.

As of 3 August 2023, a total of 244 cases of human infection with avian influenza A(H5N1) virus have been reported from four countries within the Western Pacific Region since January 2003 (Table 1). Of these cases, 136 were fatal, resulting in a case fatality rate (CFR) of 56%. The last cases in the Western Pacific Region were reported from Cambodia on 23 and 24 February 2023.

 Table 1: Cumulative number of laboratory-confirmed human cases (C) and deaths (D) of influenza A(H5N1) virus infection

 reported to WHO, by date of onset (January 2003 to 3 August 2023), Western Pacific Region

6	2003	-2009	2010-	2014	20)15	20	16	20	17	20	18	20	19	20	20	20	21	20	22	20	23	То	tal
Country	С	D	С	D	С	D	С	D	С	D	С	D	С	D	С	D	С	D	С	D	С	D	С	D
Cambodia	9	7	47	30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	58	38
China	38	25	9	5	6	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	55	32
Lao PDR	2	2	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	3	2
Viet Nam	112	57	15	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	128	64
Total	161	91	71	42	6	1	0	0	0	0	0	0	0	0	1	0	0	0	2	1	3	1	244	136

NB: This table is updated on a monthly basis following the updates from the <u>Source</u>

Globally, from January 2003 to 14 July 2023, 878 cases of human infection with avian influenza A(H5N1) virus were reported from 23 countries. Of these 878 cases, 458 were fatal (CFR of 52%) (<u>Source</u>).

Human infection with avian influenza A(H5N6) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H5N6) virus were notified to WHO in the Western Pacific Region. The last case was reported from Guilin city, Guangxi province, China, with an onset date of 3 July 2023.

To date, a total of 86 laboratory-confirmed cases of human infection with influenza A(H5N6) virus including 33 deaths (CFR 38 %) have been reported to WHO in the Western Pacific Region since 2014. The last case was reported from China with an onset of illness of 3 July 2023.

Human infection with avian influenza A(H5) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H5) virus were notified to WHO in the Western Pacific Region. The last case was reported from Viet Nam, with an onset date of 22 October 2022 (one case, no death). This is the first case of avian influenza A(H5) reported from Viet Nam since 2014; NA subtype could not be determined.

Public health risk assessment for human infection with avian influenza A(H5) viruses

Whenever avian influenza viruses are circulating in poultry, there is a risk for sporadic infection and small clusters of human cases due to exposure to infected poultry or contaminated environments. Therefore, sporadic human cases are not unexpected.

The rise in the number of reported human cases of A(H5N6) infection may reflect the continued circulation of the virus in birds, and enhanced surveillance system and diagnostic capacity as a direct outcome of the response to the COVID-19 pandemic. The zoonotic threat remains elevated due to the spread of the viruses among birds. However, the overall pandemic risk associated with A(H5) is considered not significantly changed in comparison to previous years. WHO recommends that Member States remain vigilant and consider mitigation steps to reduce human exposure to potentially infected birds to reduce the risk of additional zoonotic infection.

For information on risk assessments on Avian Influenza, see: <u>monthly risk assessment summaries</u> and <u>Assessment of risk associated with highly pathogenic avian influenza A(H5N6) virus.</u>

Human infection with avian influenza A(H3N8) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H3N8) virus were reported to WHO in the Western Pacific Region. The last case was reported from China with an onset of illness of 22 February 2023.

To date, a total of 3 laboratory-confirmed cases of human infection with influenza A(H3N8) virus with one death have been reported to WHO in the Western Pacific Region.

Human infection with avian influenza A(H7N4) virus in China

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H7N4) virus were reported to WHO in the Western Pacific Region. To date, only one laboratory-confirmed case of human infection with influenza A(H7N4) virus has been reported to WHO. This case was reported from China on 14 February 2018.

Human infection with avian influenza A(H7N9) virus in China

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H7N9) virus were reported to WHO in the Western Pacific Region. To date, a total of 1,568 laboratory-confirmed human infections with avian influenza A(H7N9) virus, including 616 fatal cases (CFR: 39%), have been reported to WHO since early 2013. The last case of human infection with avian influenza A(H7N9) reported to WHO in the Western Pacific Region was in 2019.

Of the 1,568 human infections with avian influenza A(H7N9), 33 have reported mutations in the hemagglutinin gene indicating a change to high pathogenicity in poultry. These 33 cases were from Taiwan, China (one case had a travel history to Guangdong), Guangxi, Guangdong, Hunan, Shaanxi, Hebei, Henan, Fujian, Yunnan, and Inner Mongolia. No increased transmissibility or virulence of the virus within human cases related to the HPAI A(H7N9) virus has been detected.

Human infection with avian influenza A(H9N2) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H9N2) virus were reported to WHO in the Western Pacific Region. The last case was reported from China with an onset date of 22 June 2023. To date, a total of 90 cases of human infection with avian influenza A(H9N2),

including two deaths (both with underlying conditions), have been reported to WHO in the Western Pacific Region since December 2015. Of these, 88 were reported from China and two were reported from Cambodia. The last case was reported from China, with an onset date of 22 June 2023 and has since recovered.

Human infection with avian influenza A(H10N3) virus

Between 28 July and 3 August 2023, **no new cases** of human infection with avian influenza A(H10N3) virus were reported to WHO in the Western Pacific Region. To date, two cases of avian influenza A(H10N3) virus have been reported globally. The last case was reported from Zhejiang, China with an onset date of 11 June 2022.

Most previously reported human infections with avian influenza viruses were due to exposure to infected poultry or contaminated environments. Since avian influenza viruses, including avian influenza A(H10N3) viruses, continue to be detected in poultry populations, further sporadic human cases could be detected in the future. Currently, available epidemiologic information suggests that the avian influenza A(H10N3) virus has not acquired the ability for sustained human-to-human transmission, thus the likelihood of spread among humans is low.

Animal infection with avian influenza virus

Between 28 July and 3 August 2023, no new outbreaks of highly pathogenic avian influenza among animals were notified to the World Organization for Animal Health (WOAH) from the Western Pacific Region.

For more information on animal infection with avian influenza viruses with potential public health impact, visit:

- World Organization for Animal Health (WOAH) web page: <u>Weekly disease information and Latest</u> report on Avian Influenza
- <u>Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases (EMPRES)</u>
- FAO Global Animal Disease Information System (EMPRES-i)

Other updates

- Influenza at the human-animal interface summary and assessment 14 July 2023
- <u>Assessment of risk associated with recent influenza A(H5N1) clade 2.3.4.4b viruses</u> 21 December 2022
- Recommended composition of influenza virus vaccines for use in the 2023 southern hemisphere influenza season 23 September 2022
- <u>WHO issues updated influenza vaccines position paper</u> 1 June 2022
- <u>Recommended composition of influenza virus vaccines for use in the 2023-2024 northern</u> <u>hemisphere influenza season</u> 24 February 2023
- WHO SAGE Seasonal Influenza Vaccination Recommendations during the COVID-19 Pandemic Interim guidance 20 September 2020

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BMJ Open COVID-19 case-fatality rate and demographic and socioeconomic influencers: worldwide spatial regression analysis based on countrylevel data

Yang Cao (),^{1,2} Ayako Hiyoshi,^{1,3} Scott Montgomery ()^{1,4,5}

ABSTRACT Montgomery S. COVID-19 case-

Objective To investigate the influence of demographic and socioeconomic factors on the COVID-19 case-fatality rate (CFR) globally.

Design Publicly available register-based ecological study. Setting Two hundred and nine countries/territories in the world.

Participants Aggregated data including 10 445 656 confirmed COVID-19 cases.

Primary and secondary outcome measures COVID-19 CFR and crude cause-specific death rate were calculated using country-level data from the Our World in Data website.

Results The average of country/territory-specific COVID-19

CFR is about 2%-3% worldwide and higher than previously reported at 0.7%-1.3%. A doubling in size of a population is associated with a 0.48% (95% CI 0.25% to 0.70%) increase in COVID-19 CFR, and a doubling in the proportion of female smokers is associated with a 0.55% (95% Cl 0.09% to 1.02%) increase in COVID-19 CFR. The open testing policies are associated with a 2.23% (95% CI 0.21% to 4.25%) decrease in CFR. The strictness of anti-COVID-19 measures was not statistically significantly associated with CFR overall, but the higher Stringency Index was associated with higher CFR in higher-income countries with active testing policies (regression coefficient beta=0.14, 95% CI 0.01 to 0.27). Inverse associations were found between cardiovascular disease death rate and diabetes prevalence and CFR. **Conclusion** The association between population size and COVID-19 CFR may imply the healthcare strain and lower treatment efficiency in countries with large populations. The observed association between smoking in women and COVID-19 CFR might be due to the finding that the proportion of female smokers reflected broadly the income level of a country. When testing is warranted and healthcare resources are sufficient, strict guarantine and/or lockdown measures might result in excess deaths in underprivileged populations. Spatial dependence and temporal trends in the data should be taken into account in global joint strategy and/or policy making against the COVID-19 pandemic.

INTRODUCTION

The pandemic caused by the SARS-CoV-2 virus/COVID-19, which has been initially

Strengths and limitations of this study

- This is the first study that investigated the relationship between COVID-19 case-fatality rate and demographic and socioeconomic factors globally.
- Our study addressed the question from a geospatial perspective, which may inspire new reflections to fight against the COVID-19 pandemic globally.
- Asymptomatic carriers and victims of COVID-19 were not taken into account in the analysis.
- No detailed information on time from diagnosis to death and comorbidity of the COVID-19 cases is available in the current study, which might bias the association in an unknown direction.
- Country-level analysis may conceal huge discrepancies between subnational entities in terms of both outcomes and predictors.

reported in Wuhan, a city in the Hubei province in China, in December 2019, has become a major global health concern.¹ Poor outcomes in those with COVID-19 infections correlate with clinical and laboratory features of cytokine storm syndrome, an exaggerated systemic inflammatory phenomenon due to overproduction of proinflammatory cytokines by the immune system that results in diffuse inflammatory lung disease and acute respiratory distress syndrome (ARDS).² It may be complicated by sepsis, respiratory failure, ARDS and subsequent multiorgan failure.³ Although COVID-19-related deaths are not clearly defined in the international reports available so far, many governments are warning people to be particularly stringent in following the recommended prevention measures because COVID-19 may result in severe conditions that need critical care, including ventilation or death.⁴ Untill the end of June 2020, the pandemic has resulted in over 10 million confirmed cases and 500

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000 deaths worldwide.⁵ COVID-19-related fatality rates are difficult to assess with certainty, but according to the estimates based on the data from China, the UK, Italy and the Diamond Princess cruise ship, the overall death rate from the confirmed COVID-19 cases is around 0.7%–1.3%, sharply rising from less than 0.002% in children aged 9 years or younger to 8% in people aged over 80, which is much greater than seasonal influenza at about 0.1%.^{46–10}

During the COVID-19 pandemic, numerous studies on the global public health emergency have covered a significant range of disciplines, including medicine, mathematics and social sciences. The spatial spread is one of the most important properties of COVID-19, a characteristic which mainly depends on the epidemic mechanism, human mobility and control strategy.¹¹ Spatial statistical methods are frequently used to uncover relationships between spatiotemporal patterns of infectious diseases and host or environmental characteristics,¹² to generate detailed maps to visualise the distribution of the diseases' morbidity or mortality^{13 14} and to identify hotspots, clusters and potential risk factors.^{15–18}

Clinical risk factors for mortality of adult patients with COVID-19 have been investigated in numerous studies, and the identified factors include older age¹⁹; male sex²⁰; higher sequential organ failure assessment score²¹; obesity^{22 23}; pre-existing concurrent diabetes²⁴; cardiovascular, cerebrovascular²⁵ and kidney diseases²⁶; and macroeconomic and environmental risk factors, such as socioeconomic deprivation,²⁷ air pollution²⁸ ²⁹ and diurnal temperature variation.³⁰ However, there is a lack of published studies on the effects of country-level demographic and socioeconomic characteristics on COVID-10 case-fatality rates (CFRs). It is an important issue for governments and regional or international nongovernmental organisations to identify country characteristics that are associated with high CFR and to help develop prevention and intervention measures to fight against this global public health crisis.

Using the publicly available data from the nongovernmental organisation Our World in Data,³¹ we aimed to investigate the relationship of key country-level demographic and socioeconomic indices and COVID-19 casefatality, and to explore factors associated with COVID-19 CFR, which may indicate treatment efficiency and strain in healthcare resources, while controlling for the spatial dependence of the data collected at different locations.

METHODS

Data on COVID-19 by Our World in Data

The COVID-19 dataset used in the study was downloaded from the Our World in Data website on 2 July 2020, which is a collection of the COVID-19 data maintained by the organisation Our World in Data and updated daily. The dataset includes country-level daily data on confirmed cases, deaths and testing, as well as other variables of potential interest.^{31 32} The data sources of the dataset, including the European Centre for Disease Prevention and Control, the International Organisation for Standardisation (ISO), national government reports, the Department of Economic and Social Affairs of the United Nations (UN), UN Population Division, UN Statistics Division, Oxford COVID-19 Government Response Tracker, the World Bank, the Global Burden of Disease Collaborative Network, and Eurostat of the Organisation for Economic Cooperation and Development.³¹ There are in total 34 indices from 209 countries and territories in the dataset by 2 July 2020. The dataset was linked to the global geospatial vector database using the ISO 3166-1 alpha-2 codes for the spatial modelling.³³

Case-fatality rate

CFR of COVID-19 was calculated as the number of total deaths due to COVID-19 divided by the number of total confirmed COVID-19 cases by 2 July 2020 multiplied by 100. CFR was investigated in our study because it may reflect disease severity, as well as the efficiency of treatment and healthcare response and strain. CFR is not constant. It can vary between populations and over time, depending on the interplay between the causative agent of the disease, the host and the environment, as well as available treatments and quality of patient care. For example, it can increase if the healthcare system is overwhelmed by the sudden increase of cases.³⁴

We also calculated the crude cause-specific death rate (CDR) of COVID-19 in a sensitivity analysis and compared it with CFR. The CDR was calculated as the number of total deaths due to COVID-19 divided by the production of population and months of the data collected, multiplied by $1\,000\,000$.³⁵

Statistical analysis

The numbers of confirmed cases, tests and tests per thousand people were not included in the analysis because they were depending much on the population, detection policy, and quarantine and isolation policies of the countries and territories. Instead, we included the Stringency Index in the analysis, which is a composite measure based on nine response indicators, including school closures, workplace closures, testing policy and travel bans, rescaled to a value from 0 to 100 (100=strictest response).³⁶ The Stringency Index data were obtained from the World Intellectual Property Organisation website on 1 July 2020.³⁷ Because the variable 'proportion of the population with basic handwashing facilities on premises' has missing values in more than 50% of the countries/territories, it was also excluded from the analysis.

A subcomponent of the Stringency Index is the government policy on the access to COVID-19 test by four groups: 0, no policy; 1, only those who were both symptomatic and met specific criteria; 2, anyone symptomatic; and 3, open public testing, such as drive-through testing.³⁶ The testing policy indicator was used for stratification of the analysis.

Collinearity and multiple collinearity between the variables were examined using Pearson's correlation coefficient and multiple correlation coefficient, respectively.³⁸ Spatial autocorrelation (or spatial dependence) is defined as the relationship between spatial proximity among some observational units and similarity among their values; positive spatial autocorrelation refers to situations in which the nearer the observational units, the more similar their values (and vice versa for its negative counterpart).³⁹ This feature violates the assumption of independence among observations on which many regression analyses are applied. Spatial autocorrelation among the fatality rates of the countries/territories was examined using a multivariate linear regression model and the Moran's I test.⁴⁰ The autocorrelation was visualised using the Matérn correlation coefficient.⁴¹

The Matérn correlation model, a commonly used model for spatial correlated data, was fitted for our data to investigate the relationship between COVID-19 case-fatality and the demographic and socioeconomic variables. The latitude and longitude of the centroid of the countries/territories were used as random effects in the Matérn correlation model.⁴²

Variables with skewed distribution were log-transformed before entering the regression models. The multiple imputation method was used to handle the missing values in the data. The missing values were assumed to be missing at random. A total of 10 copies of the data were created, each of which had the missing values imputed by using switching regression, an iterative multivariable regression technique. Then, each complete dataset was analysed independently. Estimates of parameters of interest were then averaged across the 10 copies to give a single estimate using Rubin's rule.⁴³

Subgroup analysis was conducted by economic levels of the countries/territories according to the World Bank's newest classification.⁴⁴

The associations of the studied variables with COVID-19 CDR (per 1000000 person-months) of the countries/ territories from 31 December 2019 to 1 July 2020 were also evaluated using the same methodology but using the Poisson regression model because of the rare event, and the results were presented in the supplemental materials.

All the analysis were conducted in R V.4.02 (the R Foundation for Statistical Computing, Vienna, Austria) using the package $spaMM^{45}$ and in Python V.3.6 (Python Software Foundation)⁴⁶ using the packages geopandas and geoplot.⁴⁷

In the study, estimates of health indicators at the global level were reported according to the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER) statement.⁴⁸

Patient and public involvement

The study is a worldwide public available register-based study; therefore, it was not required and also not possible to involve patients or the public in the design, conduct, reporting or dissemination plans of our research.

RESULTS

Descriptive characteristics of the variables

In total, 10445656 confirmed COVID-19 cases and 511030 deaths from 209 countries and territories and 17 variables (including latitude and longitude) were included in the study. The descriptive statistics of the variables are shown in table 1. The pairwise relationships of the variables are shown in figure 1. The CFR, CDR, cardiovascular disease (CVD) death rate and diabetes prevalence shown in table 1 and figure 1, and/or following tables and figures were not adjusted/standardised for age and sex; therefore, they are crude rates. High multicollinearity was found between the number of confirmed cases and population size (pairwise Pearson's r=0.76, p<0.001; figure 1), and gross domestic product (GDP) per capita and life expectancy, median age, the proportion of aged 65 years or older, the proportion of extreme poverty and hospital beds per 1000 people (all pairwise Pearson's r greater than or approximate to 0.70 and p<0.001; multiple correlation coefficient=0.92, p<0.001; figure 1). Therefore, median age, the proportion of aged 65 or older and hospital beds per 1000 people were excluded in later regression analvsis. Although the proportion of extreme poverty is an interesting factor to be investigated, it is highly correlated with GDP per capita (r=-0.83), and the latter is available in more countries; therefore, the proportion of extreme poverty was also excluded from the analysis.

Worldwide COVID-19 CFR distribution

Distribution of COVID-19 CFR of the 209 countries/ territories is shown in figure 2. The mean and median CFR worldwide are 3.31% and 2.19%, respectively (table 1), with the highest rates found in Yemen (27%), West and North Europe (14%–19%), and North America (9%–12%, figure 2).

Spatial autocorrelation of the COVID-19 CFR

Statistically significant spatial autocorrelation was found among the countries/territories' COVID-19 CFR. The residuals from the common (non-spatial) multivariate linear regression models show apparent spatial dependence around the countries/territories with high fatality (figure 3). The p value from Moran's I test for the spatial autocorrelation of the residuals is 2.32×10^{-5} .

The estimated spatial autocorrelation coefficient of COVID-19 CFR between two locations against their distance is shown in figure 4, with a strength parameter v of 2.48 and a decay parameter ρ of 0.12. This indicates that locations more than 20° (in longitude or latitude) away have an autocorrelation coefficient below 0.5 (figure 4).

Associations of demographic and socioeconomic variables with COVID-19 CFR

Overall, after controlling for the spatial dependence, the statistically significant variables associated with COVID-19 CFR are population size and proportion of female smokers in a country/region (table 2). The multivariate adjusted results indicate that, approximately, a doubling in size of

Table 1 Descriptive statistics of the variables									
	Ν	Mean	SD	Median	Min	Max	IQR		
Confirmed COVID-19 cases	209	49979	218713	2221	3	2634432	18420		
Confirmed COVID-19 cases (log)	209	7.75	2.84	7.71	1.10	14.78	4.13		
COVID-19 deaths	209	2445	11014	51	0	127410	346		
COVID-19 CFR (%)	209	3.31	3.79	2.19	0.00	26.94	3.75		
COVID-19 CDR (per 1 000 000 person- months)	209	13.98	28.75	3.31	0.00	205.84	10.94		
Population size (million)	209	37.08	142.84	6.87	0.01	1439.32	25.38		
Population size (log)	209	15.28	2.52	15.74	6.70	21.09	3.29		
GDP per capita (US\$1000)	182	19.28	19.69	13.03	0.66	116.94	23.47		
GDP per capita (log)	182	9.28	1.21	9.48	6.49	11.67	1.84		
Population density (per km) ²	198	328.16	1507.86	87.25	0.14	19347.50	176.45		
Population density (log)	198	4.42	1.52	4.47	-1.99	9.87	1.74		
CVD death rate (per 100 000)	185	256.17	116.51	242.65	79.37	724.42	153.98		
CVD death rate (log)	185	5.44	0.46	5.49	4.37	6.59	0.65		
Diabetes prevalence (%)	192	8.06	4.26	7.13	0.99	23.36	5.13		
Diabetes prevalence (log)	192	1.94	0.56	1.96	-0.01	3.15	0.67		
Stringency Index	172	44.22	9.16	45.46	7.68	65.20	11.16		
Life expectancy	206	73.47	7.54	75.07	53.28	86.75	9.91		
Median age	185	30.55	9.10	29.90	15.10	48.20	16.50		
Age 65 years or older (%)	182	8.81	6.21	6.66	1.14	27.05	10.87		
Age 65 years or older (log)	182	1.91	0.74	1.90	0.13	3.30	1.42		
Proportion of extreme poverty (%)	121	13.86	20.54	2.2	0.10	77.60	20.8		
Proportion of extreme poverty (log)	121	1.08	2.03	0.79	-2.30	4.35	4.57		
Proportion of female smoker (%)	140	10.44	10.48	6.05	0.10	44.0	17.3		
Proportion of female smoker (log)	140	1.63	1.40	1.80	-2.30	3.78	2.31		
Proportion of male smoker	138	32.62	13.71	31.30	7.70	78.10	19.90		
Hospital beds per 1000 people	164	3.01	2.46	2.36	0.10	13.80	2.63		
Hospital beds per 1000 people (log)	164	0.77	0.88	0.86	-2.30	2.62	1.11		

CDR, cause-specific death rate; CFR, case-fatality rate; CVD, cardiovascular disease; GDP, gross domestic product; ;IQR, interquartile range; SD, standard deviation.

population is associated with a 0.48% (95% CI 0.25% to 0.70%) increase in COVID-19 CFR, and a doubling in proportion of female smokers is associated with a 0.55% (95% CI 0.09% to 1.02%) increase in COVID-19 CFR. Open public testing policy is associated with decreased CFR (beta=-2.23, 95% CI -4.25 to 0.21) compared with no testing policy.

Because associations might differ by the proportion of the population aged 65 years or older (65+), we produced stratified estimates by the proportion of people aged 65+ years (see online supplemental table S1). Briefly, population size and testing policy were found to be associated with CFR in the countries with a proportion of people aged 65+ years between 5% and 10%; and GDP per capita, population size, population density and the proportion of smokers were associated with CFR in the countries with a proportion of people aged 65+ years larger than 15%.

The estimated contour of COVID-19 CFRs worldwide is shown in figure 5. The areas with the higher risks are mainly around North America and West Europe.

The subgroup analysis by economic level indicates that population size, CVD death rate and diabetes prevalence are statistically significantly associated with COVID-19 CFR in the lower-income to middle-income countries; population size, diabetes prevalence, and testing only symptomatic and specified policy and testing anyone symptomatic policy are statistically significantly associated with COVID-10 CFR in the upper-income to middleincome countries (table 2).

However, the subgroup analysis in upper-income to middle-income and high-income countries by testing policy indicates that, if testing was ensured (testing policy=2 or 3), increment in Stringency Index is associated with increased COVID-19 CFR (beta=0.14, 95% CI 0.01 to 0.27) (table 3). The finding might imply an open

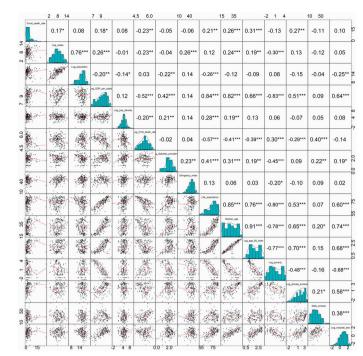


Figure 1 Pairwise scatter plots and Pearson's correlation coefficients of the variables. *P<0.05, **P<0.01, ***P<0.001.

society policy does not necessarily lead to a great CFR when testing is ensured. Meanwhile, diabetes prevalence is inversely associated with CFR (beta=-3.30, 95% CI -5.85 to 0.74).

DISCUSSION

Geospatial analysis of the COVID-19 pandemic

The COVID-19 pandemic is still full of unknowns, and many of them have a spatial dimension that leads to understanding the emergency geographically. Analysis of the COVID-19 data requires an interdisciplinary approach, including spatial statistics, that may provide important implications to policies addressing the spatial issues in the pandemic.⁴⁹ A recently published review summarised studies by 1 May 2020 on geospatial and spatial–statistical analysis of the COVID-19 pandemic. In total, 63 studies were categorised into five subjects: spatiotemporal analysis, health and social geography, environmental variables, data mining and web-based mapping.⁵⁰ Although

15 of the studies address the question globally, none of them investigated the association of COVID-19-related deaths with country-level demographic and/or socioeconomic factors. From a global health perspective, there is a knowledge gap in the research field. Our geospatial analysis fills this gap and shows the utility of the analysis to improve the understanding of the consequences of COVID-19 and their related factors from a global level, and contributes to the predictive modelling and decisionmaking to combat the pandemic.

Proportion of smokers and COVID-19 CFR

The proportion of female smokers was positively associated with COVID-19 CFR in the overall analysis, but the association diminished when the analysis was stratified by the economical level of the countries/territories. This is counterintuitive, given that severer COVID-19 was associated with male sex due to possibly immune system and hormone levels⁵¹ and smoking.^{52 53} The observed association between smoking in women and COVID-19 CFR

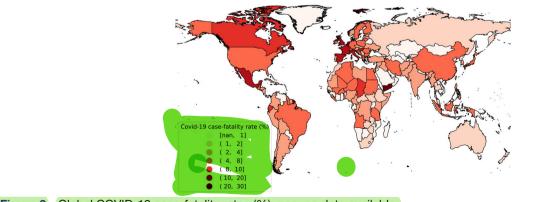


Figure 2 Global COVID-19 case-fatality rates (%). nan, no data available.

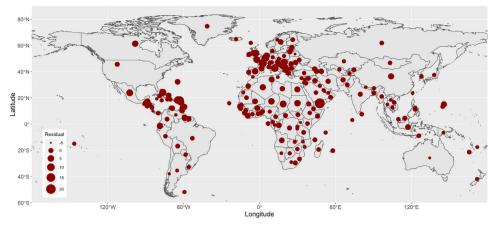


Figure 3 Residuals of the common (non-spatial) multivariate linear regression.

might be due to the finding that the proportion of female smoker reflected broadly the income level of a country (figure 6A). Linking to the theory of diffusion of innovation, the spread of smoking habit has been illustrated to take several stages of a rise, levelling and decline, from rich to poor, men to women, and young to old.^{54–56} In the early phrase, the prevalence of smoking has increased in men, and women take up smoking about a few decades later. Subsequently, male smoking starts to decline and female follows later on. This pattern has been found to spread from rich to poor countries. In general, Asian and African countries tend to have low female smoking but high male smoking, while in European countries, prevalence is similar between men and women.^{57 58} Therefore, female smoking in the overall analysis is a marker of the development of a country and it diminishes when the analysis is stratified by it.

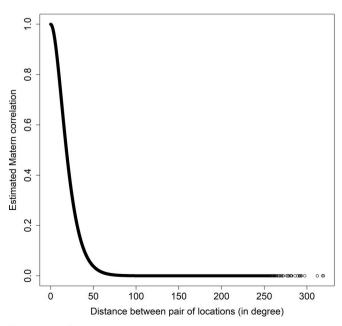


Figure 4 Strength and decay of the spatial autocorrelation between pair of locations.

Population size and density and COVID-19 CFR

Our results indicate that a larger population size is the most consistently associated with higher COVID-19 CFR (figure 6B), but population density is not associated with the outcome, controlled for some demographic and socioeconomic variables and spatial dependence worldwide. The association of population size with CFR can be interpreted in at least two ways. It could be because larger countries have experienced a greater number of deaths and have conducted relatively less test compared with countries with smaller population. Alternatively, in larger countries, healthcare might have been strained and resulted in a relatively higher number of deaths among confirmed cases than smaller countries.⁵⁹ We are unable to disentangle the mechanisms of the association. Therefore, it is recommended that the analysis is replicated by a study with more detailed healthcare information on both individual and country levels. However, in national studies, higher density has been shown to be associated with higher COVID-19 prevalence in Japan,⁶⁰ Italy⁶¹ and Iran.⁶² The lack of an association between COVID-19 CFR and population density globally might be due to the confounding by testing strategies and economic levels. In countries like Germany and South Korea, which took a more active testing strategy than, for example, the UK, where PCR test for COVID-19 was only performed among those who were with severe symptoms and were admitted to the hospital at the beginning,⁶³ CFR naturally showed lower values. There are weak but statistically significant negative associations between population size and population density (r=-0.15, p=0.042) and GDP per capita (r=-0.20, p=0.006). To minimise the confounding, we conducted a stratified analysis by economic level (table 2) and testing policy (only within upper-income and middleincome and high-income countries, table 3). Furthermore, we conducted a sensitivity analysis for CDR and the results were similar (see online supplemental tables S2, S3 and figures S1-S4). The results suggest that, globally, healthcare strain should be first relieved and treatment efficiency should be improved in countries with large populations.

Table 2 Estimation for variables' reg	pression coefficients (beta)	for CFR					
	Unadjusted		Adjusted				
Variables	Beta (95% CI)	P value	Beta (95% CI)	P value			
Overall (n=209)							
GDP per capita (log)	0.14 (-0.38 to 0.65)	0.616	0.03 (-0.68 to 0.73)	0.777			
Population (log)	0.42 (0.20 to 0.63)	<0.001	0.48 (0.25 to 0.70)	<0.001			
Population density (log)	0.01 (-0.33 to 0.35)	0.797	0.10 (-0.25 to 0.46)	0.595			
Stringency Index	-0.02 (-0.08 to 0.03)	0.460	-0.02 (-0.08 to 0.03)	0.434			
Proportion of female smokers (log)	0.47 (0.06 to 0.89)	0.040	0.55 (0.09 to 1.02)	0.034			
Proportion of male smokers	-0.02 (-0.06 to 0.02)	0.339	-0.02 (-0.06 to 0.03)	0.478			
CVD death rate (log)	-1.48 (-2.62 to -0.34)	0.017	-0.79 (-2.43 to 0.85)	0.390			
Diabetes prevalence (log)	-0.87 (-1.93 to 0.18)	0.139	-0.37 (-1.52 to 0.78)	0.480			
Testing policy							
0 (ref)							
1	-0.72 (-1.94 to 0.49)	0.266	–0.97 (–2.12 to 0.18)	0.126			
2	-1.08 (-2.47 to 0.32)	0.168	-1.23 (-2.56 to 0.10)	0.109			
3	-1.37 (-3.47 to 0.73)	0.240	-2.23 (-4.25 to -0.21)	0.043			
Low-income countries (n=29)							
GDP per capita (log)	-0.22 (-2.92 to 2.48)	0.874	0.88 (–3.73 to 5.49)	0.592			
Population (log)	0.49 (-0.98 to 1.96)	0.516	0.02 (-1.82 to 1.86)	0.428			
Population density (log)	0.31 (–1.03 to 1.65)	0.651	–0.33 (–1.61 to 0.95)	0.417			
Stringency Index	-0.01 (-0.11 to 0.08)	0.724	0.01 (-0.15 to 0.16)	0.354			
Proportion of female smokers (log)	0.53 (–0.50 to 1.55)	0.295	0.34 (–1.52 to 2.19)	0.357			
Proportion of male smokers	0.09 (0.00 to 0.19)	0.234	-0.01 (-0.22 to 0.21)	0.375			
CVD death rate (log)	1.63 (–3.80 to 7.06)	0.557	2.58 (-6.40 to 11.56)	0.396			
Diabetes prevalence (log)	0.00 (-2.01 to 2.01)	0.989	-1.01 (-2.76 to 0.74)	0.292			
Testing policy							
0 (ref)							
1	-2.52 (-4.68 to -0.36)	0.152	-0.18 (-2.82 to 2.46)	0.354			
2	-3.50 (-5.48 to -1.52)	0.018	-2.23 (-5.59 to 1.13)	0.233			
3	–2.75 (–5.48 to –0.01)	0.163	-1.00 (-6.10 to 4.10)	0.577			
Lower-indome to middle-income cou	ntries (n=44)						
GDP per capita (log)	0.74 (–0.02 to 1.5)	0.072	0.59 (–0.17 to 1.35)	0.152			
Population (log)	0.27 (0.08 to 0.46)	0.005	0.44 (0.25 to 0.62)	<0.001			
Population density (log)	0.06 (–0.23 to 0.35)	0.695	-0.08 (-0.36 to 0.20)	0.551			
Stringency Index	0.00 (-0.03 to 0.02)	0.804	0.03 (-0.01 to 0.06)	0.234			
Proportion of female smokers (log)	-0.12 (-0.48 to 0.24)	0.538	0.10 (-0.24 to 0.44)	0.418			
Proportion of male smokers	0.01 (-0.01 to 0.03)	0.436	0.02 (0.00 to 0.04)	0.184			
CVD death rate (log)	-0.61 (-1.72 to 0.50)	0.297	–1.78 (–2.98 to –0.58)	0.008			
Diabetes prevalence (log)	0.71 (-0.06 to 1.47)	0.089	1.00 (0.34 to 1.66)	0.008			
Testing policy							
0 (ref)							
1	–0.09 (–0.85 to 0.68)	0.757	–0.11 (–0.95 to 0.72)	0.644			
2	0.24 (-0.92 to 1.39)	0.691	-0.22 (-1.16 to 0.72)	0.606			
3	0.10 (-1.26 to 1.45)	0.856	-1.66 (-3.22 to -0.09)	0.051			
Upper-income to middle-income cou	. ,						
GDP per capita (log)	0.73 (–0.58 to 2.05)	0.275	–0.24 (–1.67 to 1.20)	0.549			
	· · · · /		· · · · /	Continue			

Continued

	Unadjusted		Adjusted	
/ariables	Beta (95% CI)	P value	Beta (95% CI)	P value
Population (log)	0.36 (0.04 to 0.68)	0.030	0.61 (0.24 to 0.97)	0.011
Population density (log)	-0.26 (-0.71 to 0.20)	0.275	-0.48 (-0.88 to -0.07)	0.057
Stringency Index	0.00 (-0.06 to 0.06)	0.586	0.03 (-0.03 to 0.10)	0.321
Proportion of female smokers (log)	0.03 (-0.39 to 0.44)	0.211	-0.09 (-0.53 to 0.34)	0.389
Proportion of male smokers	-0.04 (-0.09 to 0.01)	0.177	-0.01 (-0.07 to 0.04)	0.588
CVD death rate (log)	-1.12 (-2.79 to 0.56)	0.213	–0.06 (–1.73 to 1.61)	0.783
Diabetes prevalence (log)	1.74 (-0.02 to 3.50)	0.108	2.37 (0.76 to 3.98)	0.009
Testing policy				
0 (ref)				
1	-0.89 (-1.76 to -0.02)	0.086	–1.70 (–2.73 to –0.68)	0.005
2	-0.64 (-1.90 to 0.61)	0.32	-2.10 (-3.41 to -0.78)	0.007
3	0.39 (-3.30 to 4.08)	0.836	-0.99 (-4.62 to 2.64)	0.578
High-income countries (n=82)				
GDP per capita (log)	-1.05 (-3.56 to 1.46)	0.453	-1.08 (-3.49 to 1.32)	0.417
Population (log)	0.56 (0.22 to 0.90)	0.001	0.43 (0.04 to 0.81)	0.097
Population density (log)	0.16 (-0.40 to 0.72)	0.596	0.65 (0.01 to 1.28)	0.084
Stringency Index	0.07 (–0.05 to 0.20)	0.285	0.06 (-0.07 to 0.19)	0.515
Proportion of female smokers (log)	0.85 (–0.10 to 1.79)	0.177	0.53 (-0.84 to 1.91)	0.300
Proportion of male smokers	-0.04 (-0.14 to 0.06)	0.451	-0.11 (-0.22 to 0.00)	0.161
CVD death rate (log)	-2.14 (-4.49 to 0.20)	0.097	0.31 (-2.60 to 3.22)	0.567
Diabetes prevalence (log)	-2.63 (-4.77 to -0.48)	0.035	-2.26 (-5.03 to 0.50)	0.214
Testing policy				
0 (ref)				
1	1.14 (–1.59 to 3.87)	0.365	0.02 (-2.51 to 2.56)	0.541
2	0.35 (–2.52 to 3.23)	0.524	-0.11 (-2.75 to 2.54)	0.707
3	-0.49 (-4.01 to 3.04)	0.654	-0.67 (-3.98 to 2.64)	0.642

Testing policy: 0, no policy; 1, tested only symptomatic and specified; 2, tested anyone symptomatic; 3, tested open public. CFR, case-fatality rate; CVD, cardiovascular disease; GDP, gross domestic product; ref, reference.

Economic level and COVID-19 CFR

In our analysis, high COVID-19 CFR was found mainly around North America and West Europe (figure 1). One of the possible reasons might be that these countries

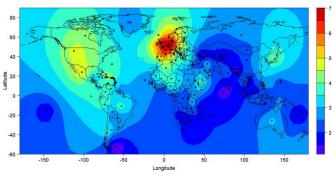


Figure 5 Contour plot of estimated COVID-19 case-fatality rate (%).

counted COVID-19 deaths by including those who died with it, not only from it.^{8 64} Determination of COVID-19 deaths also differed by country. Some countries recorded a COVID-19 death as any death once the patient became a confirmed case, even the death happened after 2 months possibly by other reasons (such as an accident), while in some other countries, a COVID-19 death was recorded as the death that occurred within a certain period (ranging from 2 to 8 weeks) after COVID-19 symptom onset.⁶⁵ Furthermore, the extent that the counting covered home, institutions and hospitals in high-income countries is different from that in low-income countries.⁶⁴

It has been reported that CFR was more favourable in low-income countries.^{64 66} There are three possibilities to explain this unusual pattern: it may be because of younger population, poor data quality or it was still the early stage (at the time of writing this paper) of COVID-19 infection.⁶⁴ There is a tight relationship between the income

 Table 3
 Estimation for variables' regression coefficients (beta) for CFR by testing policy in upper-income to middle-income and high-income countries

	Unadjusted		Adjusted	
Variables	Beta (95% CI)	P value	Beta (95% CI)	P value
Testing policy=1 (tested only symptomatic an	nd specified, n=45)			
GDP per capita (log)	0.51 (-1.05 to 2.08)	0.522	-0.22 (-2.04 to 1.61)	0.805
Population (log)	0.34 (-0.29 to 0.97)	0.290	0.32 (-0.34 to 0.99)	0.393
Population density (log)	0.49 (–0.15 to 1.13)	0.132	0.58 (–0.15 to 1.30)	0.131
Stringency Index	-0.07 (-0.22 to 0.08)	0.349	-0.06 (-0.23 to 0.10)	0.469
Proportion of female smokers (log)	0.20 (-0.96 to 1.36)	0.667	0.13 (–1.28 to 1.55)	0.409
Proportion of male smokers	-0.08 (-0.19 to 0.03)	0.186	-0.04 (-0.20 to 0.11)	0.555
CVD death rate (log)	-1.69 (-3.91 to 0.52)	0.137	-0.20 (-3.70 to 3.30)	0.798
Diabetes prevalence (log)	–0.65 (–3.52 to 2.22)	0.659	-0.82 (-4.37 to 2.73)	0.672
Testing policy=2 or 3 (tested anyone sympton	natic or anyone public, n=37)			
GDP per capita (log)	0.35 (-1.42 to 2.11)	0.706	0.45 (–1.19 to 2.09)	0.590
Population (log)	0.81 (0.38 to 1.23)	0.000	0.49 (0.03 to 0.96)	0.047
Population density (log)	0.08 (–0.55 to 0.7)	0.812	0.02 (–0.61 to 0.65)	0.913
Stringency Index	0.17 (0.05 to 0.28)	0.005	0.14 (0.01 to 0.27)	0.044
Proportion of female smokers (log)	0.70 (-0.22 to 1.61)	0.151	0.40 (–0.52 to 1.33)	0.400
Proportion of male smokers	0.00 (–0.10 to 0.10)	0.890	0.00 (–0.11 to 0.11)	0.845
CVD death rate (log)	-2.34 (-4.66 to -0.02)	0.049	-2.00 (-4.95 to 0.94)	0.189
Diabetes prevalence (log)	–2.45 (–5.21 to 0.32)	0.089	–3.30 (–5.85 to –0.74)	0.013

CFR, case-fatality rate; CVD, cardiovascular disease; GDP, gross domestic product.

level of a country and demographic structure. In 2015, many of African countries were classified as low-income, and the median age of the population was less than 20 years. About 61% of the population was 24 years or younger, and merely 3% was equal to or older than 65 years.⁶⁷ It has been shown that younger age is associated with a lower likelihood of severe COVID-19.^{468 69} However, the prevalence of risk factors such as lack of hygiene

facilities, handwashing soap and water is greater,⁶⁴ and higher viral load has been suggested to be linked to more severe disease.⁷⁰ Healthcare resources are usually low in low-income countries.⁷¹ Therefore, our finding of favourable CFR for low-income countries may be in part due to the pandemic being at an early stage (figure 6C). Finally, even before the pandemic, developing countries had challenges to collect, verify and aggregate reliable data

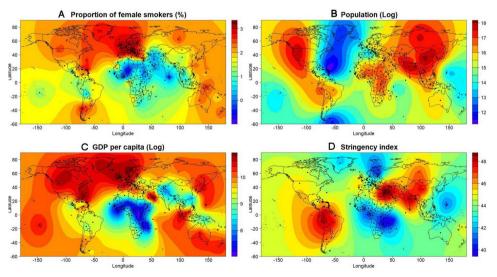


Figure 6 Contour plot of projected (A) proportion of female smoker, (B) population, (C) GDP per capita and (D) Stringency Index. GDP, gross domestic product.

epidemic and COVID-19 CFR by continent								
	Stringe	ncy Index	CFR (%	6)				
Continent	Mean	Median	Mean	Median				
Africa	41.57	43.55	2.33	1.76				
Asia	46.79	48.85	2.10	1.24				
Europe	42.57	43.70	5.15	4.25				
North America	45.71	46.42	4.28	3.10				
Oceania	42.62	40.85	1.47	0.66				
South America	49.35	51.28	2.96	2.88				

Table 4Stringency of measures against COVID-19epidemic and COVID-19 CFR by continent

CFR, case-fatality rate.

in a timely manner due to lack of resource, communication and technological development.⁷² Moreover, the pandemic might have accentuated the pre-existing challenges.⁶⁴ The extent of bias is difficult to know, including whether it is still in the early stage of infection in developing countries. Further monitoring and investigation are necessary in the future.

Stringency of measures against the COVID-19 epidemic and COVID-19 CFR

According to the currently available data from the Oxford COVID-19 Government Response Tracker,³⁶ South Americans and Asians took the strictest measures (table 4 and figure 6D), and they also had relatively lower COVID-19 CFR (table 4). However, in our multivariable analysis, which controlled for other variables and spatial dependence, we did not observe a statistically significant association between Stringency Index and COVID-19 CFR. In contrast, stricter measures were even found being associated with higher CFR in the high-income countries with active testing policies (table 3), which seems to support the current argument that lockdown measures might result in excess deaths in underprivileged populations, and those in need are hit harder by the crisis.⁷³ So far, the evidence that stricter response reduced healthcare strain or treatment efficiency reflected by COVID-19 CFR is lacking. However, the findings need to be further examined by comparing the all-cause mortalities in previous years. Meanwhile, the reliability of the Stringency Index also needs to be further investigated. The relationship between socioeconomic measures against the pandemic and COVID-19 CFR is a complicated issue which needs deeper spatiotemporal analysis with more detailed and reliable information in the future.

Noticeably, we also observed negative associations between COVID-19 CFR and CVD death rate and diabetes prevalence in some analyses, which might be partially explained by the competing risk between the deaths and/ or comorbidities,⁷⁴ because most of COVID-19 deaths are among the elderly and have one or more comorbidities.^{75–77} Therefore, the COVID-19 CFR worldwide deserves deeper investigation with more detailed comorbidity information.

Strengths and limitations

To our knowledge, this is the first study that investigated relationship between COVID-19 CFR and demographic and socioeconomic factors globally. Although numerous studies have investigated the aforementioned factors related to the COVID-19 CFR, either they investigated the question locally or they did not approach this issue from a geospatial perspective. Our study may inspire new reflections from healthcare workers to work together against the COVID-19 pandemic geographically and globally. International comparison of CFR may be challenging when the ascertainment of COVID-19 cases differed by country. To tackle this, we performed a sensitivity analysis using CDR. Although some risk factors, such as CVD and diabetes, showed different patterns of association, the population showed consistent and positive associations with COVID-19 CDR (see online supplemental tables S1 and S2).

There are many limitations in our study. First, the case fatality analysed here was based on the reported COVID-19 cases and deaths by countries/territories. According to the recent estimations, asymptomatic carriers of COVID-19 could be as high as 10%-80% in a population.⁷⁸⁻⁸³ However, this fraction was not taken into account in our analysis. Therefore, the CFRs presented in the study might be significantly higher than the real ones. In addition, there is no single globally accepted definition of COVID-19-related death; therefore, the variation in the reported values of CFR could not be fully explained, and the bias derived from the difference in the definition of COVID-19-related death between the countries could not be excluded using the data available so far. Second, the age structure of the population influences both prevalence and mortality of COVID-19; although we adjusted our analysis using the proportion of age over 65 years in populations, residual confounding largely remains. Third, no individual-level data are available in the current study; thus, results should not be extrapolated to individuallevel association. Fourth, because no diagnostic date was available in the Our World in Data, the time between diagnosis and death was not known, which could lead to variation in patient follow-up time among countries and, therefore, potential differences in CDR (because the CDR is calculated using person-time). Fifth, country-level analysis may conceal huge discrepancies between subnational entities in terms of both outcomes and predictors. The case of Northern and Southern Italy is an epitome of this. In-depth geospatial studies conducted at subnational levels are expected to provide less biassed and more actionable results. Furthermore, during an ongoing pandemic, delayed reporting occurs for both the number of cases and deaths, and strategies against the crisis also change by time. Although the analysis using data from two different time points obtained on 17 June and on 2 July produced the same results, suggesting the bias due to delayed report might be negligible; the dynamic of the problem needs to be addressed, incorporating with temporal statistics methods.

CONCLUSION

The average of country/territory-specific COVID-19 CFR is about 2%-3% worldwide, which is higher than previously reported at 0.7%-1.3% and possibly due to the unreported asymptomatic cases. The COVID-19 CFR is statistically significantly associated with population size, especially in middle-income and high-income countries, which may indicate the healthcare strain and/or lower treatment efficiency in the countries with large populations, and secondary to higher transmission risk and generally poorer health. When testing is warranted and healthcare resources are sufficient, strict quarantine and/or lockdown measures might result in excess deaths in countries with high-income level. No statistically significant findings were found in low-income countries, which might be due to the challenges in data collection, communication and verification in the countries and need to be further investigated in follow-up studies. To make global joint strategy and/or policy against the COVID-19 pandemic, spatial dependence and temporal trends must be considered in data analysis and decision making.

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RESOLUTIONS

Adopted by the World Assembly of Delegates

During the 90th General Session

21 – 25 May 2023

LIST OF RESOLUTIONS

Administrative resolutions:

- No. 1 Approval of the Director General's Report on 2022 WOAH Activities
- <u>No. 2</u> Approval of the Director General's Report on 2022 WOAH Management, Activities and Administrative Work
- <u>No. 3</u> Approval of the 2022 Financial Report (1 January 31 December 2022)
- <u>No. 4</u> Acknowledgements to the Members and Partners that made Voluntary Contributions or Subsidies to WOAH, or contributed in the Organisation of WOAH Meetings and the Provision of Personnel
- No. 5 Modification of the 2023 Budget
- <u>No. 6</u> WOAH Budgetary Incomes and Expenses for the 98th Financial Year and Related Planned Work Programme (1 January to 31 December 2024)
- <u>No. 7</u> Financial contributions from WOAH Members for 2024
- <u>No. 8</u> Renewal of the Appointment of the External Auditor
- <u>No. 9</u> Memorandum of Understanding between the World Organisation for Animal Health (WOAH) and the International Livestock Research Institute (ILRI)
- No. 10 Accession of Saint Vincent and the Grenadines to the Office International des Epizooties

Technical resolutions

- <u>No. 11</u> Recognition of the Foot and Mouth Disease Status of Members
- No. 12 Endorsement of Official Control Programmes for Foot and Mouth Disease of Members
- <u>No. 13</u> Recognition of the Contagious Bovine Pleuropneumonia Status of Members
- <u>No. 14</u> Endorsement of Official Control Programmes for Contagious Bovine Pleuropneumonia of Members
- <u>No. 15</u> Recognition of the Bovine Spongiform Encephalopathy Risk Status of Members
- <u>No. 16</u> Recognition of the African Horse Sickness Status of Members
- <u>No. 17</u> Recognition of the Peste des Petits Ruminants Status of Members
- <u>No. 18</u> Recognition of the Classical Swine Fever Status of Members
- No. 19 Endorsement of Official Control Programmes for dog-mediated rabies of Members
- <u>No. 20</u> Second addendum to Resolution No. 15 of 29 May 2020 on the "Procedures for Members for the official recognition and maintenance of animal health status of certain animal diseases or risk status of bovine spongiform encephalopathy and for the endorsement of official control programmes"
- No. 21 Amendments to the WOAH Aquatic Animal Health Code
- No. 22 Amendments to the WOAH Manual of Diagnostic Tests for Aquatic Animals
- No. 23 Amendments to the WOAH Terrestrial Animal Health Code
- No. 24 Amendments to the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- No. 25 Designation of WOAH Reference Laboratories for terrestrial and aquatic animal diseases
- No. 26 Designation of WOAH Collaborating Centres
- <u>No. 27</u> Extension to the Designation of Facilities Holding Rinderpest Virus Containing Material to Maintain Global Freedom from Rinderpest
- <u>No. 28</u> Strategic challenges in the global control of high pathogenicity avian influenza
- No. 29 Change of name of certain Sub-Regional Representations and of one Regional Commission
- <u>No. 30</u> Register of terrestrial animal diseases diagnostic kits validated and certified by WOAH
- <u>No. 31</u> Register of aquatic animal disease diagnostic kits validated and certified by WOAH

RESOLUTION Nº 1

Approval of the Director General's Report on 2022 WOAH Activities

In accordance with Article 6 of the Organic Rules of the Organisation,

THE ASSEMBLY

RESOLVES

To approve the Director General's Report on 2022 WOAH Activities (90 SG/1).

(Adopted by the World Assembly of Delegates on 23 May 2023 in view of an entry into force on 26 May 2023)

RESOLUTION No. 2

Approval of the Director General's Report on 2022 WOAH Management, Activities and Administrative Work

In accordance with Article 6 of the Organic Rules of the Organisation,

THE ASSEMBLY

RESOLVES

To approve the Director General's Report on 2022 WOAH Management, Activities and Administrative Work (90 SG/3).

(Adopted by the World Assembly of Delegates on 25 May 2023 in view of an entry into force on 26 May 2023)

Approval of the 2022 Financial Report (1 January – 31 December 2022)

In application of Article 15 of the Organic Statutes and Article 6 of the Organic Rules of WOAH,

THE ASSEMBLY

RESOLVES

To approve the Financial Report for the 96th Financial Year of WOAH (1 January – 31 December 2022) (90 SG/4).

Acknowledgements to the Members and Partners that made Voluntary Contributions or Subsidies to WOAH, or contributed in the Organisation of WOAH Meetings and the Provision of Personnel

Having noted the voluntary contributions or subsidies received by WOAH in 2022 and the in-person meetings organised by WOAH in 2022,

THE ASSEMBLY

REQUESTS

The Director General to sincerely thank:

1. Argentina, Australia, Bahrain, Canada, China (People's Rep. of), Colombia, Cyprus, Djibouti, France, Germany, Ireland, Italy, Japan, Jordan, Kazakhstan, Korea (Rep. of), Mexico, the Netherlands (through the AMR MPTF), New Zealand, Oman, Panama, Russia, Saudi Arabia, Spain, Sweden (through the AMR MPTF), Switzerland, the United Arab Emirates, the United Kingdom and the United States of America;

The European Union, Food and Agriculture Organisation of the United Nations, the World Bank and the World Health Organization;

The Bill and Melinda Gates Foundation, the Donkey Sanctuary, Four Paws, Galvmed, International Coalition for Working Equids, the International Horse Sports Confederation, the Regional International Organization for Plant Protection and Animal Health (OIRSA), the Royal Society for the Prevention of Cruelty to Animals and St Jude's Hospital;

for their voluntary contributions or subsidies to support WOAH in 2022.

2. Australia, Belgium, Bhutan, Cameroon, China (People's Rep. of), Colombia, Egypt, Ethiopia, Fiji, Georgia, Ghana, India, Indonesia, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Lebanon, Malaysia, Mongolia, Mozambique, Paraguay, Panama, Rwanda, Senegal, South Africa, Tajikistan, Tanzania, Thailand, Tunisia, the United Arab Emirates, the United States of America and Zambia;

for their contribution to the organisation of WOAH workshops that were held during 2022.

3. Australia, Canada, France, Germany, Italy, Korea (Rep. of), Norway, Panama, the United Arab Emirates, the United Kingdom and the United States of America;

for seconding national experts to WOAH in 2022.

Modification of the 2023 Budget

In accordance with Article 15 of the Organic Statutes and Article 6.h of the Organic Rules of WOAH,

Considering the variation in expenses and income for the 97th Financial Year (1 January to 31 December 2023),

THE ASSEMBLY

RESOLVES

To modify Resolution No. 6 of 26 May 2022 and replace paragraphs 1.2 a and 1.2 b of said Resolution with the following paragraphs:

1. The budget for the 97th Financial Year, for the period 1 January to 31 December 2023, is set in terms of income and expenses at EUR 19 497 600:

1.1. Income

Sections	Description	Amount EUR
Section 1	Members' contributions (Article 11 - Organic Statutes and Article 14 - Organic Rules)	$12\ 873\ 000$
	Extraordinary contributions	918 100
	Sub-total Section 1	13 791 100
	Registration fees (General Session, conferences)	-
	Publication sales	-
	Fees for evaluation of sanitary status applications	140 000
Section 2	World Fund overheads	1 400 000
	Internal contributions	$845\ 000$
	Other operating revenue	$2\ 266\ 500$
	Sub-total Section 2	4 651 500
	Investment income	20 000
	Extraordinary income	-
Section 3	Recovery of investment subsidies	33 000
	Reversal of provisions	417 000
	Sub-total Section 3	470 000
	SUB-TOTAL	18 912 600
	Carry over 2020	585 000
	TOTAL	19 497 600

- 6 -	
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Budgetary chapters		Amount EUR
1.	Information Management	4 302 150
2.	Standard Setting and Implementation	2 628 400
3.	Capacity Building	21 000
4.	Global Frameworks	832 900
5.	International Collaboration	0
6.	Institutional Governance	3 396 680
7.	General Administration	5 655 790
8.	Regional and sub-regional Representations	1 608 800
9.	Depreciation and Amortisation Expenses	1 051 880
	TOTAL	19 497 600

1.2. Expenses by budgetary chapters

WOAH Budgetary Incomes and Expenses for the 98th Financial Year and Related Planned Work Programme (1 January to 31 December 2024)

In accordance with Article 15 of the Organic Statutes and Article 6.h of the Organic Rules of WOAH,

CONSIDERING the Seventh Strategic Plan of WOAH, established for the 2021-2025 period,

THE ASSEMBLY, ON THE PROPOSAL OF THE COUNCIL

- 1) DECIDES
 - 1.1) To approve the Planned Work Programme for 2024 (90 SG/6), subject to prioritisation by the Council to ensure that expenditure remains within the allotted budget.
 - 1.2) That the budget for the 98th Financial Year, for the period from 1 January to 31 December 2024, shall be set in terms of income and expenses at EUR 18 848 600 and established as follows:

a. Income		
Sections	Description	Amount EUR
Section 1	Member contributions (Article 11 - Organic Statutes and Article 14 - Organic Rules)	14 804 000
	Extraordinary contributions	817 000
	Sub-total Section 1	15 621 000
	Registration fees (General Session, conferences)	-
	Publication sales	-
	Fees for evaluating disease status dossiers	140 000
Section 2	World Fund overheads	1 400 000
	Internal contributions	820 000
	Other operating revenue	$295\ 215$
	Sub-total Section 2	$2\ 655\ 215$
	Investment income	$51\ 885$
	Extraordinary income	-
Section 3	Recovery of investment subsidies	$32\ 500$
	Reversal of provisions	488 000
	Sub-total Section 3	572 385
	TOTAL	18 848 600

b.	Expenses by Budgetary Chapters	
Bu	dgetary Chapters	Amount EUR
1.	Information Management	$2\ 825\ 100$
2.	Standard Setting and Implementation	2 667 000
3.	Capacity Building	21 000
4.	Global Frameworks	995 000
5.	International Collaboration	0
6.	Institutional Governance	3 531 000
7.	General Administration	$5\ 844\ 500$
8.	Regional and Sub-Regional Representations	$1\ 665\ 000$
9.	Depreciation and Amortisation Expenses	1 300 000
	TOTAL	18 848 600

2) RECOMMENDS THAT

Members provide the necessary support to allow the Planned Work Programme to be carried out, in the form of payment of both statutory contributions and, when possible, voluntary contributions to the Regular Budget and/or to the World Animal Health and Welfare Fund, or any other form of support to WOAH activities.

Financial contributions from WOAH Members for 2024

In accordance with Article 11 of the Organic Statutes and Article 14 of the Organic Rules,

CONSIDERING

Resolution No. 8 dated 1 June 2001 related to contributions by the Least Developed Countries (LDC),

Resolution No. 11 of 30 May 2014 creating two categories of extraordinary contributions,

The recommendation from the WOAH Council for Members to endorse a 15% increase in statutory contributions for 2024,

The financial summary report titled "Director General's financial outlook" sent to all WOAH Delegates on 27 April 2023,

THE ASSEMBLY

DECIDES

1) that the annual statutory contribution from WOAH Members for the 2024 Financial Year are as follows:

Category	Annual total contribution
1 st category	295 025 EUR
2 nd category	236 020 EUR
3 rd category	177 015 EUR
4 th category	118 010 EUR
5 th category	$59\ 005\ \mathrm{EUR}$
6 th category	35 403 EUR

that, in accordance with the six-category scale, WOAH will only call for 50% of the total contributions due from the Members classified as Least Developed Countries (LDCs) by the Economic and Social Council of the United Nations.

2) that Members, while retaining the choice of category in which they are registered, may contribute to one of the two extraordinary categories for 2024. In this case, the concerned Members shall be exempt from their statutory contribution for the year in question.

The two extraordinary categories of contribution to be paid as a lump sum are as follows:

Category A: EUR 500 000 minimum

Category B: EUR 300 000 minimum

Renewal of the Appointment of the External Auditor

In accordance with Article 12.1. of the Financial Regulations concerning the appointment of the External Auditor and the renewal of his mandate,

THE ASSEMBLY

RESOLVES

To renew for a one year period the appointment of Mr Didier Selles of the *Cour des comptes* (French Court of auditors) as External Auditor of WOAH Accounts to audit the 2023 accounts.

Memorandum of Understanding between the World Organisation for Animal Health (WOAH) and the International Livestock Research Institute (ILRI)

CONSIDERING

The Agreement between the World Organisation for Animal Health (WOAH) and the International Livestock Research Institute (ILRI) signed on 12 March 2004,

That it is desirable, in the general interest of all concerned, that the scope and the modalities of cooperation be redefined between WOAH and ILRI,

The Memorandum of Understanding between WOAH and ILRI (90 SG/15) was approved following the deliberations of the Council on 1 March 2023,

THE ASSEMBLY

DECIDES

To approve the terms of this Memorandum of Understanding and its signature by the Director General on behalf of WOAH.

Accession of Saint Vincent and the Grenadines to the Office International des Epizooties

HAVING REGARD TO

Article 6 of the International Agreement,

The Organic Rules, particularly article 3 designating the organs in charge of the functioning of the Organisation, and article 5 stating that the Organisation is under the authority and the control of the Assembly,

The General Rules, particularly article 1 stating that the Assembly is the highest authority of the Organisation and that its wishes shall be expressed by Resolutions, as well as article 50 stating that decisions related to the applications for accession received from 31 May 2013 are based on a two thirds majority,

The Resolution No. 11 of 31 May 2013 establishing a procedure for examination of applications for accession to the Organisation, applicable only to membership applications received from 31 May 2013,

The application of Saint Vincent and the Grenadines dated 13 October 2022,

CONSIDERING

The decision of the Council at its meeting held on 28 February 2023, which was expressed unanimously in favour of the accession of Saint Vincent and the Grenadines to the *Office International des Epizooties*.

THE ASSEMBLY

RESOLVES

To accept the application for accession of Saint Vincent and the Grenadines to become a Member of the *Office International des Epizooties*.

Recognition of the Foot and Mouth Disease Status of Members

CONSIDERING THAT

- 1. During the 62nd General Session, the World Assembly of Delegates (the Assembly) established a procedure for annually updating a List of Members and zones recognised as free from foot and mouth disease (FMD) according to the provisions of the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status for certain animal diseases, including FMD,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for evaluation of official recognition of animal health status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal animal health status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from FMD,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members recognised as FMD-free where vaccination is not practised, according to the provisions of Chapter 8.8. of the *Terrestrial Code*:

2. The Director General publish the following List of Members recognised as FMD-free where vaccination is practised, according to the provisions of Chapter 8.8. of the Terrestrial Code:

Paraguay, Uruguay

- The Director General publish the following List of Members having FMD-free zones⁹ where 3. vaccination is not practised, according to the provisions of Chapter 8.8. of the *Terrestrial Code*:
- one zone designated by the Delegate of Argentina in a document addressed to Argentina: the Director General in January 2007;

the summer pasture zone in the Province of San Juan as designated by the Delegate of Argentina in a document addressed to the Director General in April 2011;

Patagonia Norte A as designated by the Delegate of Argentina in a document addressed to the Director General in October 2013;

Bolivia: one zone in the Macro-region of the Altiplano designated by the Delegate of Bolivia in documents addressed to the Director General in November 2011;

> one zone consisting of the Department of Beni and the northern part of the Department of La Paz merged with the zone consisting of the Department of Pando (August 2018), as designated by the Delegate of Bolivia in a document addressed to the Director General in September 2022;

Including Faroe Islands and Greenland.

Including Åland Islands.

³ Including French Guiana, Guadeloupe, Martinique, Réunion, Saint Pierre and Miquelon.

⁴ Including Azores and Madeira.

Excluding Kosovo administered by the United Nations. 5

Including Balearic Islands and Canary Islands.

⁷ Including Guernsey (incl. Alderney and Sark), Isle of Man, Jersey and Falkland Islands (Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) [see resolution 2065 (XX) of the General Assembly of the United Nations]). Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

⁹ For detailed information on the delimitation of zones of Members recognised as free from FMD, enquiries should be addressed to the Director General of WOAH.

Botswana:	four zones designated by the Delegate of Botswana in documents addressed the Director General in August and November 2014 as follows:	
	 one zone consisting of Zones 3c (Dukwi), 4b, 5, 6a, 8, 9, 10, 11, 12 and 13; one zone consisting of Zone 3c (Maitengwe); one zone covering Zone 4a; 	
	- one zone covering Zone 6b, with the exclusion of the containment zone as designated by the Delegate of Botswana in documents addressed to the Director General in November 2022 and February 2023;	
	one zone covering Zone 3b designated by the Delegate of Botswana in a document addressed to the Director General in August 2016;	
	one zone covering Zone 7 designated by the Delegate of Botswana in a document addressed to the Director General in August 2018;	
Brazil:	State of Santa Catarina designated by the Delegate of Brazil in a document addressed to the Director General in February 2007;	
	three zones of Brazil as designated by the Delegate of Brazil in a document addressed to the Director General in August 2020 as follows:	
	- State of Paraná;	
	 State of Rio Grande do Sul; one zone (Block 1) including the States of Acre and Rondônia and 14 municipalities in the State of Amazonas and five municipalities in the State of Mato Grosso; 	
Chinese Taipei:	one zone covering Taiwan, Penghu and Matsu areas, as designated by the Delegate of Chinese Taipei in a document addressed to the Director General in September 2019;	
Colombia:	one zone designated by the Delegate of Colombia in documents addressed to the Director General in November 1995 and in April 1996 (Area I - Northwest region of Chocó Department);	
	one zone designated by the Delegate of Colombia in documents addressed to the Director General in January 2008 (Archipelago de San Andrés and Providencia);	
Ecuador:	one zone consisting of the insular territory of the Galápagos, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;	
Malaysia:	one zone covering the provinces of Sabah and Sarawak as designated by the Delegate of Malaysia in a document addressed to the Director General in December 2003;	
Moldova:	one zone designated by the Delegate of Moldova in a document addressed to the Director General in July 2008;	
Namibia:	one zone designated by the Delegate of Namibia in a document addressed to the Director General in February 1997;	
Russia:	one zone designated by the Delegate of Russia in documents addressed to the Director General in August 2015 and March 2016;	

- 4. The Director General publish the following List of Members having FMD-free zones¹⁰ where vaccination is practised, according to the provisions of Chapter 8.8. of the *Terrestrial Code*:
- Argentina: two separate zones designated by the Delegate of Argentina in documents addressed to the Director General in March 2007 and October 2013, and in August 2010 and February 2014;
- Bolivia: one zone covering the regions of Chaco, Valles and parts of Amazonas and Altiplano as designated by the Delegate of Bolivia in documents addressed to the Director General in October 2013, February 2014 and August 2018;
- Brazil: one zone consisting of two merged zones designated by the Delegate of Brazil in documents addressed to the Director General in August 2010, September 2017 and September 2019, covering the States of Alagoas, Amapá, Amazonas, Bahia, Ceará, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Maranhão, Minas Gerais, Pará, Paraíba, Pernambuco, Piauí, Rio de Janeiro, Rio Grande do Norte, Roraima, São Paulo, Sergipe, Tocantins and Distrito Federal, with the exclusion of the municipalities of the States of Amazonas and Mato Grosso that are part of the zone of Block 1 (free from FMD where vaccination is not practised) as addressed to the Director General in August 2020;
- Chinese Taipei: one zone consisting of Kinmen County as designated by the Delegate of Chinese Taipei in a document addressed to the Director General in September 2017;
- Colombia: three separate zones designated by the Delegate of Colombia in documents addressed to the Director General in September 2019 as follows:
 - Zone I (Northern border) consisting of Departments of La Guajira, Cesar and part of the Department of Norte de Santander;
 - Zone III (Trade) consisting of the Departments of Atlántico, Córdoba, Magdalena, Sucre and part of Antioquia, Bolívar and Chocó Departments;
 - Zone IV (Rest of the country), consisting of the Departments of Amazonas, Caldas, Caquetá, Cauca, Casanare, Cundinamarca, Guainía, Guaviare, Huila, Meta, Nariño, Quindío, Putumayo, Risaralda, Santander, Tolima, Valle del Cauca, Vaupés and part of Antioquia, Bolívar, Boyacá, and Chocó Departments,

one zone consisting of two merged zones designated by the Delegate of Colombia in documents addressed to the Director General in September 2019 and in August 2020, which includes Zone II (Eastern border) and the former high surveillance zone covering the Departments of Arauca and Vichada and the municipality of Cubará of the Department of Boyacá;

one zone, namely Protection Zone I (PZ I) covering 29 municipalities of the Department of Norte de Santander, as designated by the Delegate of Colombia in a document addressed to the Director General in September 2022;

Ecuador: one zone consisting of the continental Ecuador, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;

¹⁰ For detailed information on the delimitation of zones of Members recognised as free from FMD, enquiries should be addressed to the Director General of WOAH.

- Kazakhstan: five separate zones designated by the Delegate of Kazakhstan in documents addressed to the Director General in August 2016 as follows:
 - Zone 1 consisting of Almaty region;
 - Zone 2 consisting of East Kazakhstan region;
 - Zone 3 including part of Kyzylorda region, northern part of South Kazakhstan region, northern and central parts of Zhambyl region;
 - Zone 4 including southern part of Kyzylorda region and south-western part of South Kazakhstan region;
 - Zone 5 including south-eastern part of South Kazakhstan region and southern part of Zhambyl region;
- Russia: two zones of Russia as designated by the Delegate of Russia in documents addressed to the Director General in August 2020 as follows:
 - Zone-South including Southern and North Caucasian Federal Districts, consisting of 13 Subjects: Rostov Oblast, Stavropol Krai, Krasnodar Krai, Volgograd Oblast, Astrakhan Oblast, Republic of Kalmykia, Chechen Republic, Republic of Ingushetia, Republic of Dagestan, Kabardino-Balkarian Republic, Karachay-Cherkess Republic, Republic of North Ossetia-Alania, Republic of Adygea;
 - Zone-Sakhalin consisting of the Island of Sakhalin and the Kurile Islands;

one zone of Eastern Siberia consisting of two Subjects (Republic of Tuva and Republic of Buryatia) and one Raion of the Republic of Altai (Kosh-Agachsky Raion) designated by the Delegate of Russia in a document addressed to the Director General in August 2021;

one zone, namely Zone V 'Far East' consisting of five Subjects: Amur Oblast, Jewish Autonomous Oblast, Primorsky Krai, Khabarovsky Krai, Zabaykalsky Krai, as designated by the Delegate of Russia in a document addressed to the Director General in September 2022;

Türkiye (Rep. of): one zone designated by the Delegate of Türkiye (Rep. of) in a document addressed to the Director General in November 2009.

AND

5. The Delegates of these Members shall immediately notify the WOAH Headquarters if FMD occurs in their countries or free zones within their territories.

Endorsement of Official Control Programmes for Foot and Mouth Disease of Members

CONSIDERING THAT

- 1. During the 79th General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 19 establishing a new step in the procedure for recognising the foot and mouth disease (FMD) status of a Member, namely the endorsement by WOAH of an official control programme for FMD being in compliance with the provisions of the chapter on FMD in the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve endorsement of their official control programme for FMD,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for endorsement of their official control programme for FMD to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of the endorsement of Members' official control programme for FMD based on inaccurate information or non-reporting to WOAH Headquarters of significant changes in the implementation of relevant measures in the Member subsequent to the time of endorsement of the official control programme for FMD,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members with an endorsed official control programme for FMD, according to the provisions of Chapter 8.8. of the *Terrestrial Code*:

Botswana	Kyrgyzstan	Namibia
China (People's Rep. of)	Morocco	Thailand
India		

2. The Delegates of these Members shall notify WOAH Headquarters the occurrence of FMD, changes in the epidemiological situation and other significant events in their countries or territories in accordance with Chapter 1.1. of the *Terrestrial Code*.

Recognition of the Contagious Bovine Pleuropneumonia Status of Members

CONSIDERING THAT

- 1. During the 71st General Session, the World Assembly of Delegates (the Assembly) established a procedure for annually updating a List of Members and zones recognised as free from contagious bovine pleuropneumonia (CBPP) according to the provisions of the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status for certain diseases, including CBPP,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for evaluation of official recognition of animal health status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal animal health status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from CBPP,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members recognised as CBPP-free according to the provisions of Chapter 11.5. of the *Terrestrial Code*:

Argentina	Eswatini	Peru
Australia	France ¹¹	$Portugal^{12}$
Bolivia	India	Russia
Botswana	Italy	Singapore
Brazil	Mexico	South Africa
Canada	Mongolia	Switzerland
China (People's Rep. of)	New Caledonia	United States of America
Colombia	Paraguay	Uruguay
Ecuador		

- 2. The Director General publish the following List of Members having a CBPP-free zone¹³ according to the provisions of Chapter 11.5. of the *Terrestrial Code*:
 - Namibia: one zone located south of the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in October 2015;

AND

3. The Delegates of these Members shall immediately notify the WOAH Headquarters if CBPP occurs in their countries or free zone within their territories.

¹¹ Including French Guiana, Guadeloupe, Martinique, Mayotte, and Réunion.

¹² Including Azores and Madeira.

¹³ For detailed information on the delimitation of the zone of the Member recognised as free from CBPP, enquiries should be addressed to the Director General of WOAH.

Endorsement of Official Control Programmes for Contagious Bovine Pleuropneumonia of Members

CONSIDERING THAT

- 1. During the 82nd General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 31 establishing the endorsement by WOAH of an official control programme for contagious bovine pleuropneumonia (CBPP), in accordance with the relevant provisions of the chapter on CBPP in the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve endorsement of their official control programme for CBPP,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for endorsement of their official control programme for CBPP to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of the endorsement of Members' official control programme for CBPP based on inaccurate information or non-reporting to WOAH Headquarters of significant changes in the implementation of relevant measures in the Member subsequent to the time of endorsement of the official control programme for CBPP,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members with an endorsed official control programme for CBPP, according to the provisions of Chapter 11.5. of the *Terrestrial Code*:

Namibia Zambia

2. The Delegates of these Members shall notify WOAH Headquarters the occurrence of CBPP, changes in the epidemiological situation and other significant events in their countries or territories in accordance with Chapter 1.1. of the *Terrestrial Code*.

Recognition of the Bovine Spongiform Encephalopathy Risk Status of Members

CONSIDERING THAT

- 1. During the 67th General Session, the World Assembly of Delegates (the Assembly) established a procedure for annually updating a List of Members and zones, categorised by their bovine spongiform encephalopathy (BSE) risk according to the provisions of the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status of certain diseases, including BSE risk status,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for evaluation of official recognition of BSE risk status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal risk status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of the BSE risk status,

THE ASSEMBLY

RESOLVES THAT

1. The Director General published the following List of Members recognised as having a negligible BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code*:

Argentina Australia Austria Belgium Bolivia Brazil Bulgaria Canada Chile Colombia Costa Rica Croatia Cyprus Czech Republic	Denmark Estonia Finland ¹⁴ France Germany Hungary Iceland India Ireland Israel Italy Japan Korea (Rep. of)	Latvia Liechtenstein Lithuania Luxembourg Malta Mexico Namibia New Zealand Nicaragua Norway Panama Paraguay Peru	Poland Portugal ¹⁵ Romania Serbia ¹⁶ Singapore Slovakia Slovenia Spain ¹⁷ Sweden Switzerland The Netherlands United States of America Uruguay
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2. The Director General publish the following List of Members recognised as having a controlled BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code*:

Chinese Taipei	Greece
Ecuador	Russia

3. The Director General publish the following List of Members with zones¹⁸ recognised as having a negligible BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code*:

China (People's Rep. of): a zone designated by the Delegate of China (People's Rep. of) in a document addressed to the Director General in November 2013, consisting of the People's Republic of China, with the exclusion of Hong Kong and Macau;

United Kingdom: one zone consisting of Northern Ireland as designated by the Delegate of the United Kingdom in a document addressed to the Director General in September 2016;

one zone consisting of Jersey as designated by the Delegate of the United Kingdom in a document addressed to the Director General in August 2019;

- 4. The Director General published the following List of Members with zones¹⁸ recognised as having a controlled BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code*:
 - United Kingdom: one zone consisting of England and Wales as designated by the Delegate of the United Kingdom in documents addressed to the Director General in September and October 2016 and in November 2021;

one zone consisting of Scotland as designated by the Delegate of the United Kingdom in documents addressed to the Director General in September and October 2016 and in December 2018;

AND

5. The Delegates of these Members shall immediately notify WOAH Headquarters if BSE occurs in their countries or zones within their territories.

¹⁴ Including Åland Islands.

¹⁵ Including Azores and Madeira.

¹⁶ Excluding Kosovo administered by the United Nations.

¹⁷ Including Balearic Islands and Canary Islands.

¹⁸ For detailed information on the delimitation of the zones of the Members recognised as having a negligible or controlled BSE risk, enquiries should be addressed to the Director General of WOAH.

Recognition of the African Horse Sickness Status of Members

CONSIDERING THAT

- 1. During the 80th General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 19, which amended the chapter of the Terrestrial Animal Health Code (Terrestrial Code) on African horse sickness (AHS). These standards provide a pathway for Members or zones to be recognised by WOAH as free from AHS,
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status for certain animal diseases, including AHS,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified and updated the financial implications for Members applying for evaluation of official recognition of animal health status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal animal health status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from AHS,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members recognised as AHS-free according to the provisions of Chapter 12.1. of the *Terrestrial Code*:

25	
40	

AND

2. The Delegates of these Members shall immediately notify WOAH Headquarters if AHS occurs in their countries or their territories.

¹⁹ Including Hong Kong and Macau.

²⁰ Including Åland Islands.

²¹ Including French Guiana, Guadeloupe, Martinique, Mayotte, Réunion, Saint Barthélémy, Saint Martin, Saint Pierre and Miquelon.

²² Including Azores and Madeira.

²³ Including Balearic Islands and Canary Islands.

²⁴ Including Cayman Islands, Guernsey (incl. Alderney and Sark), Isle of Man, Jersey, Saint Helena and Falkland Islands (Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) [see resolution 2065 (XX) of the General Assembly of the United Nations]).

²⁵ Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

Recognition of the Peste des Petits Ruminants Status of Members

CONSIDERING THAT

- 1. During the 81st General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 29, which amended the chapter of the *Terrestrial Animal Health Code* (*Terrestrial Code*) on peste des petits ruminants (PPR). These standards provide a pathway for Members or zones to be recognised by WOAH as free from PPR,
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status for certain animal diseases, including PPR,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16 which specified and updated the financial implications for Members applying for evaluation of official recognition of animal health status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal animal health status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from PPR,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members recognised as PPR-free according to the provisions of Chapter 14.7. of the *Terrestrial Code*:

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Argentina Australia Austria Belgium Bolivia Bosnia and Herzegovina Botswana Brazil Canada Chile Chinese Taipei Colombia Croatia Cyprus Czech Republic	Denmark Ecuador Estonia Eswatini Finland ²⁶ France ²⁷ Germany Greece Hungary Iceland Ireland Italy Korea (Rep. of) Latvia Lesotho	Liechtenstein Lithuania Luxembourg Madagascar Malta Mauritius Mexico New Caledonia New Zealand North Macedonia (Rep. of) Norway Paraguay Peru Philippines Poland	Portugal ²⁸ Romania Russia Singapore Slovakia Slovenia South Africa Spain ²⁹ Sweden Switzerland The Netherlands United Kingdom ³⁰ United States of America ³¹ Uruguay
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- 2. The Director General publish the following List of Members having a PPR-free zone³² according to the provisions of Chapter 14.7. of the *Terrestrial Code*:
 - Namibia: one zone located south of the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in November 2014;

AND

3. The Delegates of these Members shall immediately notify WOAH Headquarters if PPR occurs in their countries or free zone within their territories.

²⁶ Including Åland Islands.

²⁷ Including French Guiana, Guadeloupe, Martinique, Réunion, Saint Barthélémy, Saint Martin, Saint Pierre and Miquelon.

²⁸ Including Azores and Madeira.

²⁹ Including Balearic Islands and Canary Islands.

³⁰ Including Cayman Islands, Guernsey (incl. Alderney and Sark), Isle of Man, Jersey, Saint Helena and Falkland Islands (Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) [see resolution 2065 (XX) of the General Assembly of the United Nations]).

³¹ Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

³² For detailed information on the delimitation of the zone of the Member recognised as free from PPR, enquiries should be addressed to the Director General of WOAH.

Recognition of the Classical Swine Fever Status of Members

CONSIDERING THAT

- 1. During the 81st General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 29, which amended the chapter of the *Terrestrial Animal Health Code* (*Terrestrial Code*) on classical swine fever (CSF). These standards provide a pathway for Members or zones to be recognised by WOAH as free from CSF,
- 2. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified and updated the procedure for Members to follow to achieve official recognition and maintenance of status for certain animal diseases, including CSF,
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16 which specified and updated the financial implications for Members applying for evaluation of official recognition of animal health status to meet part of the costs defrayed by WOAH in the evaluation process,
- 4. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 5. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 6. During the 86th General Session, the Assembly noted an explanatory document outlining the standard operating procedure for official recognition of animal health status of non-contiguous territories as part of a Member already having an official animal health status. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of Members' or zonal animal health status based on inaccurate information or untimely reporting to WOAH Headquarters of changes in epidemiological status or other significant events subsequent to the time of declaration of freedom from CSF,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members recognised as CSF-free according to the provisions of Chapter 15.2. of the *Terrestrial Code*:

Argentina Australia Austria Belgium Bulgaria Canada Chile Costa Rica Croatia Czech Republic Denmark Finland ³³ France ³⁴	Germany Hungary Ireland Italy Latvia Liechtenstein Luxembourg Malta Mexico New Caledonia New Zealand Norway	Paraguay Poland Portugal ³⁵ Slovakia Slovenia Spain ³⁶ Sweden Switzerland The Netherlands United Kingdom ³⁷ United States of America ³⁸ Uruguay
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- 2. The Director General publish the following List of Members having CSF-free zones³⁹ according to the provisions of Chapter 15.2. of the *Terrestrial Code*:
 - Brazil: one zone composed of the States of Rio Grande do Sul and Santa Catarina as designated by the Delegate of Brazil in a document addressed to the Director General in September 2014;

one zone covering the States of Acre, Bahia, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Rio de Janeiro, Rondônia, São Paulo, Sergipe and Tocantins, Distrito Federal, and the municipalities of Guajará, Boca do Acre, South of the municipality of Canutama and Southwest of the municipality of Lábrea in the State of Amazonas as designated by the Delegate of Brazil in a document addressed to the Director General in September 2015 and in October 2020;

one zone consisting of the State of Paraná as designated by the Delegate of Brazil in a document addressed to the Director General in October 2020;

Colombia: one zone designated by the Delegate of Colombia in a document addressed to the Director General in September 2015;

the central-eastern zone as designated by the Delegate of Colombia in a document addressed to the Director General in October 2020;

Ecuador: one zone consisting of the insular territory of the Galápagos as designated by the Delegate of Ecuador in a document addressed to the Director General in October 2018;

AND

3. The Delegates of these Members shall immediately notify the WOAH Headquarters if CSF occurs in their countries or free zones within their territories.

³³ Including Åland Islands.

³⁴ Including French Guiana, Guadeloupe, Martinique, Mayotte and Réunion.

³⁵ Including Azores and Madeira.

³⁶ Including Balearic Islands and Canary Islands.

³⁷ Including Guernsey (incl. Alderney and Sark), Isle of Man and Jersey.

³⁸ Including Guam, Puerto Rico and US Virgin Islands.

³⁹ For detailed information on the delimitation of the zones of the Members recognised as free from CSF, enquiries should be addressed to the Director General of WOAH.

Endorsement of Official Control Programmes for dog-mediated rabies of Members

CONSIDERING THAT

- 1. During the 84th General Session, the World Assembly of Delegates (the Assembly) adopted Resolution No. 26, which confirmed Members' commitment towards the elimination of dogmediated rabies by 2030,
- 2. During the 87th General Session, the Assembly adopted Resolution No. 27 establishing the endorsement by WOAH of an official control programme for dog-mediated rabies, in accordance with the relevant provisions of the chapter on infection with rabies virus in the *Terrestrial Animal Health Code* (*Terrestrial Code*),
- 3. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 15, which specified the procedure for Members to follow to achieve endorsement of their official control programme for dog-mediated rabies,
- 4. Through the Adapted Procedure 2020, the Assembly adopted Resolution No. 16, which specified the financial implications for Members applying for endorsement of their official control programme for dog-mediated rabies to meet part of the costs defrayed by WOAH in the evaluation process,
- 5. During the 79th General Session, the Assembly noted that an explanatory document outlining the standard operating procedures for official animal health status evaluations had been compiled by WOAH Headquarters for the benefit of Members,
- 6. During the 85th General Session, the Assembly noted a complete revision of the standard operating procedures providing further details on the process of official status recognition. The document has been published on the WOAH website,
- 7. Information published by WOAH is derived from declarations made by the Delegates of Members. WOAH is not responsible for the publication and maintenance of the endorsement of Members' official control programme for dog-mediated rabies based on inaccurate information or non-reporting to WOAH Headquarters of significant changes in the implementation of relevant measures in the Member subsequent to the time of endorsement of the official control programme for dog-mediated rabies,

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following List of Members with an endorsed official control programme for dog-mediated rabies, according to the provisions of Chapter 8.14. of the *Terrestrial Code*:

Namibia Philippines Zambia	Namibia	Philippines	Zambia
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2. The Delegates of these Members shall notify WOAH Headquarters the occurrence of dogmediated rabies, changes in the epidemiological situation and other significant events in their countries or territories in accordance with Chapter 1.1. of the *Terrestrial Code*.

Second addendum to Resolution No. 15 of 29 May 2020 on the "Procedures for Members for the official recognition and maintenance of animal health status of certain animal diseases or risk status of bovine spongiform encephalopathy and for the endorsement of official control programmes"

CONSIDERING THAT

- 1. During the Adapted Procedure 2020, the World Assembly of Delegates (the Assembly) adopted Resolution No. 15, which described the procedures that Members should follow to achieve the official recognition and maintenance of animal health status of certain animal diseases or risk status of bovine spongiform encephalopathy (BSE) and for the endorsement of official control programmes,
- 2. During the 90th General Session, the Assembly adopted Resolution No. 23, which included in the *Terrestrial Animal Health Code* the revised provisions on BSE and on the application for official recognition by WOAH of risk status for BSE,

THE ASSEMBLY

DECIDES THAT

- the evaluation of the applications for the official recognition and the annual reconfirmation of BSE risk status will be based on the revised provisions adopted during the 90th General Session, beginning from the annual cycle of May 2024 – May 2025;
- 2. the maintenance of the BSE risk status, should a case of BSE occur in a Member or zone recognised as posing a negligible or controlled risk for BSE, will be defined based on the revised provisions adopted during the 90th General Session, immediately after their entry into force as defined in the Resolution No. 23;
- 3. this Resolution No. 20 complements Resolution No. 15 adopted during the Adapted Procedure 2020 and Resolution No. 22 adopted at the 88th General Session, which remains in force.

Amendments to the WOAH Aquatic Animal Health Code

CONSIDERING THAT

- 1. The content of the WOAH *Aquatic Animal Health Code* (the *Aquatic Code*) is the result of modifications made by the World Assembly of Delegates during previous WOAH General Sessions,
- 2. It is necessary to update the *Aquatic Code* in accordance with amendments proposed by the WOAH Aquatic Animal Health Standards Commission (Annexes 4, 5, 6, 7, 8, 9, 10, 11 and 12 of Document 90 SG/10/CS4), after consultation with the World Assembly of Delegates.

THE ASSEMBLY

RESOLVES

- 1. To adopt the updates to the *Aquatic Code* proposed in Annexes 4, 5, 6, 7, 9, 10, 11 and 12 of Document 90 SG/10/CS4 in English, French and Spanish, each text being authentic;
- 2. To adopt the updates to the *Aquatic Code* proposed in Annex 8 of Document 90 SG/10/CS4 in English, French and Spanish, each text being authentic, with the following modifications:
 - 2.1. In Annex 8 (Chapter 10.X. Infection with tilapia lake virus):
 - a) In Article 10.X.3., to place points 1 and 2 under study.
 - b) In Article 10.X.5., to place the final paragraph under study.
 - c) In Article 10.X.6., to place the final paragraph under study.
- 3. To ask the Director General to publish the adopted texts in a revised edition of the *Aquatic Code* with appropriate numbering and formatting.

Amendments to the WOAH Manual of Diagnostic Tests for Aquatic Animals

CONSIDERING THAT

- 1. The content of the WOAH *Manual of Diagnostic Tests for Aquatic Animals* (the *Aquatic Manual*) is the result of modifications made by the World Assembly of Delegates during previous WOAH General Sessions,
- 2. It is necessary to update the *Aquatic Manual* in accordance with amendments proposed by the WOAH Aquatic Animal Health Standards Commission (Annexes 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32 and 33 of Document 90 SG/10/CS4), after consultation with the World Assembly of Delegates.

THE ASSEMBLY

RESOLVES

1. To adopt the following updates to the *Aquatic Manual* chapters proposed in the Annexes of Document 90 SG/10/CS4 in English, the text being authentic;

Chapter 2.2.1. Acute hepatopancreatic necrosis diseases (Annex 22)

Chapter 2.2.3. Infection with *Hepatobacter penaei* (necrotising hepatopancreatitis) (Annex 23)

Chapter 2.2.4. Infection with infectious hypodermal and haematopoietic necrosis virus (Annex 24)

Chapter 2.2.5. Infection with infectious myonecrosis virus (Annex 25)

Chapter 2.2.7. Infection with Taura syndrome virus (Annex 26)

Chapter 2.2.8. Infection with White spot syndrome virus (Annex 27)

Chapter 2.3.1. Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome) (Annex 28)

With the amendments approved by the Assembly:

In Table 4.4.2 Primer and probe sequences for the conventional polymerase chain reaction (PCR), method 1, correct the cycling parameters by deleting the repetition of "95°C/30 sec," after "56°C/45 sec" and "72°C/2.5 min"

In method 2, correct the second cycling condition by changing "65°C/45 sec" to "65°C/30 sec"

Chapter 2.3.2. Infection with epizootic haematopoietic necrosis virus (Annex 29)

With the amendments approved by the Assembly:

In Table 4.4.2 Primer and probe sequences for the conventional PCR, correct the cycling parameters by adding "94°C/30 sec" before "50°C/30 sec" and adding "72°C/1 min" after "50°C/30 sec"

Section 2.2.1 of Chapter 2.3.9. Infection with spring viraemia of carp virus (Annex 30) Sections 2.2.1 and 2.2.2 of Chapter 2.4.2 Infection with *Bonamia exitiosa* (Annex 31) Sections 2.2.1 and 2.2.2 of Chapter 2.4.3 Infection with *Bonamia ostreae* (Annex 32) Sections 2.2.1 and 2.2.2 of Chapter 2.4.4 Infection with *Marteilia refringens* (Annex 33)

2. To ask the Director General to publish the adopted text in a revised edition of the *Aquatic Manual* with appropriate numbering and formatting.

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RESOLUTION No. 23

Amendments to the WOAH Terrestrial Animal Health Code

CONSIDERING THAT

- 1. The content of the WOAH *Terrestrial Animal Health Code* (the *Terrestrial Code*) is the result of modifications made by the World Assembly of Delegates at previous WOAH General Sessions;
- 2. It is necessary to update the *Terrestrial Code* in accordance with amendments proposed by the WOAH Terrestrial Animal Health Standards Commission (Annexes 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22 of Document 90 SG/10/CS1), after consultation with the World Assembly of Delegates.

THE ASSEMBLY

RESOLVES

- 1. To adopt the updates to the *Terrestrial Code* proposed in Annexes 4, 5, 7, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21 and 22 of Document 90 SG/10/CS1 in English, French and Spanish, each text being authentic;
- 2. To adopt the updates to the *Terrestrial Code* proposed in Annexes 6, 9, 12 and 13 of Document 90 SG/10/CS1 in English, French and Spanish, each text being authentic, with the following modifications:
 - 2.1. In Annex 6 (Chapter 7.8.)
 - a) Remove the proposal to delete the definition for 'Suffering'.
 - 2.2. In Annex 9 (Chapter 8.14.)
 - a) Remove the proposed Article 8.14.6bis. and the proposed amendments to Article 8.14.7.
 - 2.3. In Annex 12 (Chapter 11.4.)
 - a) In Article 11.4.3., in point 4,

add 'or food' after 'feed'.

b) In Article 11.4.5bis., in the first paragraph,

replace 'Articles 11.4.3. or 11.4.4.' with 'point 4 of Article 11.4.3.'.

c) In the English version only, in Article 11.4.10., in point 3 c) i),

add 'were' before 'derived'.

d) In Article 11.4.18., in point 2, in the second paragraph,

replace 'a downer (non-ambulatory)' with 'unable to rise or walk without assistance'.

e) In the English and Spanish versions only, in Article 11.4.18., in points 2 a), 2 c) and 2 d),

add 'clinical' before 'presentation' and "clínico" after "cuadro", respectively.

f) In Article 11.4.18., in point 2 c),

replace 'presented as downers (non-ambulatory)' with 'unable to rise or walk without assistance'.

- 2.4. In Annex 13 (Chapter 1.8.)
 - a) In Article 1.8.5., in point 2 a) iv), in the first paragraph,

replace 'BSE agents' with 'the classical BSE agent'.

b) In Article 1.8.5., in point 2 a) v), in the first paragraph,

replace 'BSE agents' with 'the classical BSE agent'.

c) In Article 1.8.6., in Table 1, point (C),

replace 'presented as downers (non-ambulatory)' with 'unable to rise or walk without assistance'.

3. To ask the Director General to publish the adopted texts in a revised edition of the *Terrestrial Code* with appropriate numbering and formatting.

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RESOLUTION No. 24

Amendments to the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CONSIDERING THAT

- 1. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual), like the Terrestrial Animal Health Code, is an important contribution to the international harmonisation of sanitary standards related to terrestrial animals and animal products,
- 2. Members were asked for the comments of their specialists for each new or revised chapter of the *Terrestrial Manual* before it was finalised by the Biological Standards Commission,

THE ASSEMBLY

RESOLVES

1. To adopt the following texts for the *Terrestrial Manual*:

Glossary of terms

- 1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases
- 1.1.10. Veterinary vaccines

With the amendments approved by the Assembly:

In lines 33–34, *Summary*, to delete the words "unless shelf-life can be extended by appropriate testing and subject to approval by the relevant regulatory authority" after the words "must be discarded and destroyed"

3.1.1. Anthrax

With the amendments approved by the Assembly:

In line 44, Section A *Introduction*, to add the words "and anus" after the word "nostril" and the words "(for example plugged with cotton wool or other suitable material soaked in an approved disinfectant)" after the words "should be closed"

- 3.1.5. Crimean–Congo haemorrhagic fever
- 3.1.18. Rabies (infection with rabies virus and other lyssaviruses)
- 3.1.19. Rift Valley fever (infection with Rift Valley fever virus)

With the amendments approved by the Assembly:

In lines 20–21, *Summary*, to add the words "using correct personal protective equipment" after "biocontainment measures", and delete the sentence "It is recommended that laboratory workers be vaccinated if possible."

In lines 86–88, Section A *Introduction*, to add "work under strict biosafety and biocontainment environments where they use correct personal protective equipment to protect themselves against possible infection" after "Staff should" and delete "be vaccinated when a vaccine is available".

3.1.22. Trichinellosis (infection with *Trichinella* spp.)

- 3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*)
- 3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus* plutonius)

With the amendments approved by the Assembly:

In line 10, Summary, to delete the sentence "Both disease signs and the presence of M. plutonius are required for diagnosis." and reinstate the text "Most infected colonies display few visible signs."

3.3.10. Fowlpox

With the amendments approved by the Assembly:

In Table 1. Test methods available for diagnosis of fowl pox and their purpose, to change the rating of the PCR from "+" to "-" for the purpose "Prevalence of infection – surveillance"

3.3.13. Marek's disease

With the amendments approved by the Assembly:

In line 86, Section A Introduction, to replace the word "ovary" with "gonads"

In Table 1 *Features useful in differentiating Marek's disease, lymphoid leukosis and reticuloendotheliosis*, to replace "Neural involvement" with "Peripheral nerves" in the description of microscopic lesions, and to replace "Diffuse" with "Focal/multifocal in layers or diffuse in broiler breeders" in the row describing splenic lesions in Marek's disease.

3.4.12. Lumpy skin disease

With the amendments approved by the Assembly:

In lines 82–83, Section A *Introduction*, to delete the sentence "Some wildlife species are susceptible to LSD."

- 3.7.2. Rabbit haemorrhagic disease
- 3.9.7. Influenza A virus of swine

With the amendments approved by the Assembly:

In line 399, Section B.1.6 *Reverse-transcription polymerase chain reaction*, to replace the word "discriminate" with "differentiate" twice in the sentence.

3.10.1. Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean-Congo haemorrhagic fever)

With the amendments approved by the Assembly:

In lines 536–537, Section B2.4.1.1 *Infection inhibition in microtitre plates*, to replace the word "plaques" with "lesions".

2. To request the Director General to publish the adopted texts in the *Terrestrial Manual*.

Designation of WOAH Reference Laboratories for terrestrial and aquatic animal diseases

CONSIDERING THAT

- 1. WOAH's *Basic Texts* provide the Terms of Reference, designation criteria, and internal rules for WOAH Reference Laboratories,
- 2. The Terms of Reference of the WOAH Biological Standards Commission and the Aquatic Animal Health Standards Commission include the responsibility to examine applications from Members relating to the creation of new WOAH Reference Laboratories with activities corresponding to the Commissions' scientific mandate and report its findings to the Director General,
- 3. All WOAH Reference Laboratory applications are assessed by the appropriate WOAH Specialist Commission using standardised criteria that include: the institution's ability, capacity and readiness to provide services; the scientific and technical standing of the institution concerned at the national and international levels; the quality of its scientific and technical leadership including internationally recognised expertise; the institution's prospective stability in terms of personnel, activity and funding; the technical relevance of the institution and its activities to WOAH's programme priorities,
- 4. Details of the applicant laboratories that have been assessed by the WOAH Biological Standards Commission or the Aquatic Animal Health Standards Commission are published in the reports of the meetings of the Commissions,
- 5. All Reference Laboratory applications are endorsed by the WOAH Council,
- 6. Proposals for a major change in a WOAH Reference Laboratory follow the same procedure,
- 7. Article 4 of the Internal Rules for WOAH Reference Centres states that "Applications endorsed by the Council shall be presented to the Assembly for approval",

THE ASSEMBLY

RESOLVES

To designate the following new WOAH Reference Laboratories for terrestrial and aquatic animal diseases and add them to the list of WOAH Reference Laboratories (available on the WOAH web site):

WOAH *Reference Laboratory for lumpy skin disease* Exotic and vector-borne diseases (EXOVEC), Department of infectious diseases in animals, Sciensano, Uccle, BELGIUM

WOAH *Reference Laboratory for American foulbrood (infection of honey bees with* Paenibacillus larvae)

Animal Health Laboratory, Diagnostic and Surveillance Services, Biosecurity New Zealand, Ministry for Primary Industries, Upper Hutt, NEW ZEALAND

WOAH Reference Laboratory for varroosis of honey bees

Animal Health Laboratory, Diagnostic and Surveillance Services, Biosecurity New Zealand, Ministry for Primary Industries, Upper Hutt, NEW ZEALAND

WOAH Reference Laboratory for mammalian tuberculosis

Centro de Vigilancia Sanitaria Veterinaria (VISAVET), Universidad Complutense de Madrid, Madrid, SPAIN

Designation of WOAH Collaborating Centres

CONSIDERING THAT

- 1. The WOAH's *Basic Texts* provide the Terms of Reference, designation criteria, and internal rules for WOAH Collaborating Centres,
- 2. The Terms of Reference of each of the four elected WOAH Specialist Commissions include the responsibility to examine applications from Members relating to the designation of new WOAH Collaborating Centres with activities corresponding to the Commission's area of expertise,
- 3. All WOAH Collaborating Centre applications are assessed by the appropriate WOAH Specialist Commission using standardised criteria that include: the institution's ability, capacity and readiness to provide services; the scientific and technical standing of the institution concerned at the national and international levels; the quality of its scientific and technical leadership including internationally recognised expertise; the institution's prospective stability in terms of personnel, activity and funding; and the technical and geographical relevance of the institution and its activities to WOAH's programme priorities,
- 4. Details of the applicant institutions that have been assessed by a Specialist Commission are published in the reports of the meeting of the Commission,
- 5. All Collaborating Centre applications are assessed by the corresponding Regional Commission and endorsed by the WOAH Council,
- 6. Proposals for a major change in a WOAH Collaborating Centre follow the same procedure,
- 7. Article 4 of the Internal Rules for WOAH Reference Centres states that "Applications endorsed by the Council shall be presented to the Assembly for approval".

THE ASSEMBLY

RESOLVES

To designate the following new WOAH Collaborating Centres and add them to the list of WOAH Collaborating Centres (available on the WOAH web site):

WOAH Collaborating Centre for Wildlife Health Risk Management Wildlife Health Australia (WHA), Cammeraigal/Dharawal Country, Mosman, New South Wales, AUSTRALIA

WOAH Collaborating Centre for Quality Control of Veterinary Vaccines in the Middle East The Central Laboratory for Evaluation of Veterinary Biologics (CLEVB), Abbasia, Cairo, EGYPT WOAH Collaborating Centre for Day-One Veterinary Competencies in the Middle East Faculty of Veterinary Medicine, Cairo University, Oula, Giza District, Giza Governorate, EGYPT

WOAH Collaborating Centre for Economics of Animal Health in the Americas Region comprising the following consortium members:

Department of Agricultural Economics, Kansas State University, UNITED STATES OF AMERICA

Department of Economics, Business and Sociology (ESALQ/USP), University of São Paulo, and Faculty of Agronomy and Veterinary Medicine, University of Brasília, BRAZIL

Department of Business, Economics and Rural Development, Faculty of Veterinary Medicine and Husbandry, Universidad Nacional Autonoma De México, MEXICO

School of Economic Sciences, Paul G. Allen School for Global Health, Washington State University, UNITED STATES OF AMERICA

Extension to the Designation of Facilities Holding Rinderpest Virus Containing Material to Maintain Global Freedom from Rinderpest

ACKNOWLEDGING the declaration of global freedom from rinderpest in May 2011 and the commitment made by Members to maintaining this status, reaffirmed through WOAH Resolution No. 21 (2017),

REITERATING the importance of reducing the risk posed by rinderpest virus containing material stocks through its safe destruction, including all the non-essential material held by designated facilities (hereinafter 'Rinderpest Holding Facilities'),

CONSIDERING THAT

- 1. Resolution No. 23 (2014) requested the Director General to put in place, jointly with FAO, a system to designate, inspect, monitor and evaluate Rinderpest Holding Facilities,
- 2. Resolution No. 24 (2019) extended the designation of the Rinderpest Holding Facilities first designated through Resolution No. 25 (2015) for a three-year period,
- 3. Resolution No. 23 (2019) designated two new Rinderpest Holding Facilities for a three-year period.
- 4. Resolution No. 22 (2022) extended the designation of all the previously designated Rinderpest Holding Facilities for a one-year period.
- 5. An international team carried out site inspections of five FAO-WOAH designated Rinderpest Holding Facilities in four countries in 2022,
- 6. In the absence of a site inspection, the remaining two FAO-WOAH designated Rinderpest Holding Facilities provided a written report on the previous designation period to demonstrate compliance with their mandate and agreed to receive a site inspection in 2024.

THE ASSEMBLY RECOMMENDS THAT

Members destroy all rinderpest virus containing material held within and outside FAO-WOAH designated Rinderpest Holding Facilities, with the exception of vaccine seed, manufactured vaccines, and essential diagnostic materials used by WOAH Reference Laboratories for rinderpest.

RESOLVES

To extend the designation of the following facilities as approved for holding rinderpest virus containing material for the period of three years, on behalf of the WOAH, and subject to equivalent action by FAO.

A) Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks:

- 1. African Union Pan African Veterinary Vaccine Centre (AU-PANVAC), Debre-Zeit, Ethiopia.
- 2. Centre de coopération internationale en recherche agronomique pour le développement (CIRAD), Montpellier, France.
- 3. China Institute of Veterinary Drug Control/China Veterinary Culture Collection Center (IVDC), Beijing, People's Republic of China.
- 4. High Containment Facilities of Exotic Diseases Research Station, National Institute of Animal Health, Kodaira, Tokyo, Japan.
- 5. USDA-APHIS, Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York, United States of America.
- 6. The Pirbright Institute, Surrey, United Kingdom.

B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production:

- 1. African Union Pan African Veterinary Vaccine Centre (AU-PANVAC), Debre-Zeit, Ethiopia.
- 2. Centre de coopération internationale en recherche agronomique pour le développement (CIRAD), Montpellier, France.
- 3. China Institute of Veterinary Drug Control/China Veterinary Culture Collection Center (IVDC), Beijing, People's Republic of China.
- 4. Building for Safety Evaluation Research, Production Center for Biologicals; Building for Biologics, Research and Development (storage), National Institute of Animal Health, Tsukuba, Ibaraki, Japan.

<u>Appendix</u>

Mandate for a Facility Designated to Hold Rinderpest Virus Containing Material

The facilities designated by FAO and WOAH to hold rinderpest virus (RPV)-containing material⁴⁰ (hereinafter 'Rinderpest Holding Facilities') have a mandate which justifies their function and ensures safe storage of this material.

The Rinderpest Holding Facility has a separate mandate and approval mechanism to that of a WOAH Reference Laboratory for rinderpest and a FAO Reference Centre for morbillivirus.

Although the decision to designate a Rinderpest Holding Facility lies with the WOAH World Assembly of Delegates, the Member's WOAH Delegate must support the application and be fully aware of the Mandate, and the country hosting the Rinderpest Holding Facility should have an up-to-date contingency plan for rinderpest.

The following text describes the Mandates of the two categories of Rinderpest Holding Facility:

- A) Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks.
- B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production.

A) Rinderpest virus holding facilities for storing rinderpest virus containing material, excluding vaccine stocks:

- 1. To retain an up-to-date inventory of RPV-containing material and sequence data (including recording entry and exit of this material into and out of the facility), and to share this information with FAO and WOAH through the designated web-based system.
- 2. To send an annual report to FAO and WOAH through the designated web-based system.
- 3. To safely hold RPV-containing material at an appropriate level of biocontainment and ensure appropriate measures are taken to prevent its accidental or deliberate release.
- 4. To accept RPV-containing material from FAO and WOAH Members for safe storage and/or for destruction.

⁴⁰ *RPV-containing material* means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other material from animals known or suspected to be infected; laboratory-generated diagnostic material containing live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus RNA and its cDNA copies. Subgenomic fragments of RPV genome (either as plasmid or incorporated into recombinant viruses) that cannot be incorporated into a replicating morbillivirus or morbillivirus-like virus are not considered to be RPV-containing material, neither are sera that have been either heat-treated to at least 56°C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay.

- 5. To notify FAO and WOAH before receiving RPV-containing material from other institutes for FAO to assist in shipping if needed and to ensure chain of custody.
- 6. To provide RPV-containing material to other institutes for the research or vaccine manufacture that has been approved by FAO and WOAH.
- 7. To contribute, when requested by FAO and WOAH, to the Global Rinderpest Action Plan and the global rinderpest vaccine reserve.
- 8. To maintain a system of quality assurance, biosafety and biosecurity, and to notify FAO and WOAH, should a breach of biocontainment happen, with or without release of RPV-containing material.
- 9. To notify immediately FAO and WOAH of any release or contamination of RPV-containing material in other virus stock or material stored at the facility.
- 10. To seek approval from FAO and WOAH before manipulating RPV-containing materials for the purposes of research or any other purposes, including in private sector institutions, or before shipping RPV-containing materials to other institutes.
- 11. To work towards an ever-reducing inventory of RPV-containing material from the time of adoption of the resolution, aiming to keep only critical material (diagnostic material) to safeguard the global freedom.
- 12. To participate in scientific meetings in its capacity as FAO-WOAH Rinderpest Holding Facility and using that title.
- 13. To undergo regular inspections and inventory audits by FAO and WOAH, at the institute's expense, to ensure that storage is secure and that safe operating conditions are met.
- 14. To fully cooperate by providing all the relevant reports and information when FAO and WOAH carry out a site inspection.
- 15. To provide technical advice or training to personnel from other FAO and WOAH Member Countries on the destruction, safe shipment of RPV-containing material, and/or decontamination of facilities.
- 16. To establish and maintain a network with other Rinderpest Holding Facilities.

B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production:

- 1. To retain an up-to-date inventory of vaccine stocks including current and expired vaccines and any materials solely for vaccine production and to share such information with FAO and WOAH through the designated web-based system.
- 2. To send an annual report to FAO and WOAH through the designated web-based system.
- 3. To validate or destroy stocks of expired vaccines and to share such information with FAO and WOAH through the designated web-based system.

- 4. To accept vaccine virus seeds or stocks from FAO and WOAH Member Countries for safe storage and/or for destruction.
- 5. To notify FAO and WOAH before receiving RPV-containing material from other institutes for FAO to assist in shipping if needed and to ensure the chain of custody.
- 6. To provide vaccine virus seeds or vaccines to other institutes (public or private sector) for research or vaccine manufacture that has been approved by FAO and WOAH.
- 7. To contribute, when requested by FAO and WOAH, to the global rinderpest vaccine reserve and the Global Rinderpest Action Plan, including through the emergency manufacture and preparation of vaccines in accordance with WOAH standards and the FAO-WOAH Criteria for Rinderpest Vaccine Manufacturers.
- 8. To maintain a system of quality assurance, biosafety and biosecurity, and to notify FAO and WOAH, should a breach of biocontainment happen, with or without release of RPV-containing material.
- 9. To notify immediately FAO and WOAH of any release or contamination of RPV-containing material in other virus stock or material stored at the facility.
- 10. To seek approval from FAO and WOAH before manipulating RPV-containing materials for the purposes of vaccine production or any other purposes, or before shipping RPV-containing materials to other institutes.
- 11. To regularly test the quality of the vaccines in accordance with the WOAH guidelines.
- 12. To maintain and follow procedures approved by FAO and WOAH for managing vaccine stocks (storing packaged and manufactured vaccine).
- 13. To work towards an ever-reducing inventory of RPV-containing material from the time of adoption of the resolution, aiming to keep only the critical material (vaccine seed and manufactured vaccines) to safeguard the global freedom.
- 14. To undergo regular inspections and inventory audits by FAO and WOAH, at the institute's expense, to ensure that storage is secure and that safe operating conditions are met.
- 15. To fully cooperate by providing all the relevant reports and information when FAO and WOAH carry out a site inspection.
- 16. To establish and maintain a network with other Rinderpest Holding Facilities.

Strategic challenges in the global control of high pathogenicity avian influenza

CONSIDERING THAT

- 1. The global recurrence, spread and significant increase of high pathogenicity avian influenza (HPAI) outbreaks is affecting domestic and wild birds, and some terrestrial and aquatic mammals, reflecting a distinct change in the epidemiology and ecology of the virus and posing a threat to animal health, public health, food security and biodiversity.
- 2. Conventional control measures of biosecurity, stamping out and movement restrictions, while important, can be insufficient and unsustainable given the global variation in production systems, the persistent threat of new incursions, and the high viral load present in the environment due to the ubiquitous sources of the virus.
- 3. The impact of the disease and mass culling of poultry result in substantial economic losses in production and associated industries, generating long-lasting effects on farmers' livelihoods and their mental health, high costs for government, and societal and environmental concerns.
- 4. Vaccination with high quality registered vaccines that are effective against circulating field strains can provide an extra layer of protection and reduce the quantities of the virus and the risk of further spread. Vaccination requires the adaptation of surveillance for early detection, demonstration of freedom from HPAI and monitoring of changes in circulating strains. In accordance with WOAH international standards, the use of vaccination will not affect the status of a country or zone free from high pathogenicity avian influenza if its surveillance supports the absence of infection.
- 5. WOAH international standards provide science-based recommendations to prevent the international spread of HPAI. However, concerns regarding international trade restrictions have hampered the pursuit and implementation of effective control tools and approaches, such as zoning, compartmentalisation and vaccination for HPAI control in domestic birds, which are already recommended in the adopted standards.
- 6. Avian influenza is identified as a priority disease by GF-TADs and most regions have mechanisms in place to promote regular exchange of information and best practices among risk managers to coordinate disease control policies and build science-based national control strategies.
- 7. Both the GF-TADs global strategy (2021-2025) and the Quadripartite One Health Joint Plan of Action provide frameworks to promote and foster enhanced collaboration between partners and stakeholders in animal health, wildlife health and public health, at global, regional and national levels.
- 8. The WOAH Reference Laboratory Network on animal influenza and its Collaborating Centres support Members by improving the quality of laboratory tests (LPAI, HPAI) and vaccines, providing scientific and technical assistance, and expert advice on avian influenza diagnosis and control.
- 9. OFFLU (FAO-WOAH network of expertise on animal influenza) is a well-established global network providing technical advice, expertise and training to improve diagnosis and surveillance for animal influenza and collaborates closely with WHO on issues related to the human-animal-environment interface.

THE ASSEMBLY

RECOMMENDS THAT

- 1. Members maintain transparency through timely and comprehensive reporting of avian influenza events to WOAH as described in the *Terrestrial Animal Health Code*.
- 2. Members promptly share samples and virus isolates, virus sequence data, and associated epidemiological information with WOAH Reference Laboratories, OFFLU and deposit sequences in publicly available databases to inform risk managers, thus enabling early detection, rapid response and pandemic preparedness through monitoring the evolution of LPAI and HPAI viruses.
- 3. WOAH, in collaboration with WOAH Reference Centres and OFFLU, assess the gaps in global coverage by national reference laboratories for animal influenza, identify ways to address capacity gaps, and ensure the sustainability of laboratories in under-resourced countries.
- 4. Members, with the support of WOAH, the WOAH Working Group on Wildlife, WOAH Reference Centres and OFFLU, conduct appropriate, risk-based, comprehensive and systematic monitoring and surveillance in domestic birds, wild birds (e.g., along flyways) and in other susceptible animal species to support early warning and risk management at the human-animal-environment interface.
- 5. Members intensify the exchange of relevant information and coordination with public health authorities and other relevant authorities.
- 6. Members support poultry keepers, in particular smallholders, in implementing correct usage of disease preventive and control tools, such as enhanced biosecurity, early identification of clinical signs and reporting, to prevent the introduction and spread of HPAI.
- 7. Members respect and implement the adopted WOAH standards and recognise compliant zones and compartments of their trade partners.
- 8. Members, in consultation with the poultry sector may consider the implementation of vaccination as a complementary disease control tool that is based on sound surveillance and takes into account local factors such as circulating virus strains, risk assessment and vaccination implementation conditions.
- 9. Members adopt vaccine best practices (stewardship) and reassess on an ongoing basis the use of appropriately field matched vaccine strains and the continuing need for update of vaccines.
- 10. Members respect and implement the adopted WOAH standards and recognise compliant use of vaccination without negative consequences on trade, when the vaccination programme is supported by vaccination monitoring and disease surveillance systems that can demonstrate the effectiveness of vaccination and absence of infection.
- 11. WOAH, with the support of its Reference Laboratories and OFFLU, provide up-to-date information to Members, the poultry sector and vaccine manufacturers on the genetic and antigenic characterisation of circulating virus strains, including comparison with existing vaccines, to infer levels of protection.
- 12. Members ensure the use of authorised vaccines manufactured according to WOAH standards that are effective against circulating strains and regularly share information related to the effectiveness of the vaccination programme and their surveillance system to inform changes in vaccination strategies and policy.

- 13. WOAH closely follow the changes in LPAI and HPAI virus ecology, epidemiology, validated sampling (e.g., novel technologies and environmental sampling) and diagnostic methods, to ensure the WOAH Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals are up to date with the latest science and feedback from implementation.
- 14. WOAH, in partnership with other international organisations and the private sector, develop guidance considering different production systems, to support the implementation of standards, such as on biosecurity, surveillance including vaccinated populations, and on the implementation of vaccination, zoning and compartmentalisation.
- 15. Members develop and implement national disease control and operational plans in cooperation and coordination with wildlife health authorities, public health authorities and the private sector to ensure a multi-stakeholder effort to combat HPAI.
- 16. WOAH continue working with the Quadripartite partners to assess and address barriers to intersectoral collaboration and promote the One Health approach to mitigate the risks of avian influenza.
- 17. WOAH, in collaboration with FAO, under the coordinating mechanism of GF-TADs, promote global and regional coordination by updating the global strategy for the prevention and control of HPAI, and support regional coordination initiatives, such as the Standing Group of Experts, to strengthen expert networks, build capacity, exchange epidemiological information, share best practices and provide policy and technical support among and between regions.
- 18. WOAH, its Members and the private sector support research alliances and global research coordination mechanisms (e.g. STAR-IDAZ, WHO Public Health Research Agenda, OFFLU) to generate scientific knowledge using interdisciplinary approaches and tools, including the development, testing, production and approval of effective vaccines to contribute to the successful control of HPAI.
- 19. WOAH and its Members advocate for increased investment in low- and middle-income countries from funding institutions, the private sector, resource partners and development agencies in support of strengthening the human resource capacity and sustainable infrastructure of Veterinary Services, including diagnostic capability and early warning systems.

Change of name of certain Sub-Regional Representations and of one Regional Commission

CONSIDERING

- 1. The Basic Texts that organise the functioning of the Regional and Sub-Regional Representations, especially article 33 of the General Rules, as well as the relevant resolutions or other texts,
- 2. The 7th Strategic Plan of WOAH (2021-2025), adopted by the Assembly on 27 May 2021, in particular the strategic objective regarding the "Review the business model of the Regional Representations",
- 3. The Basic Texts that organise the functioning of the Regional Commissions, especially article 13 of the General Rules,

AND CONSIDERING

- 4. It is desirable, to have consistency in the terminology used in the names of WOAH institutions,
- 5. The opinion of the Council, expressed at its meetings of September 2022 and February 2023, in favour of modifying the names of certain Sub Regional Representations to better reflect the relevant geographical coverage, and aligning the name of the Regional Commission with the name of the respective region.

THE ASSEMBLY, ON THE PROPOSAL OF THE COUNCIL,

DECIDES

1. To change the names of three Sub-Regional Representations as follows:

	CURRENT NAME			NEW NAME
(i)	Sub-Regional Dhabi	Representation in	Abu	Sub-Regional Representation for the Arabian Gulf
(ii)	Sub-Regional Central Ameri	-	for	Sub-Regional Representation for Central America and the Caribbean
(iii)	Sub-Regional Eastern Africa	Representation and the Horn of Afr	for rica	Sub-Regional Representation for Eastern Africa

2. To align the name of the Regional Commission for Asia, the Far East and Oceania with the name of the corresponding Regional Representation and hence change its name to *Regional Commission for Asia and the Pacific*.

Register of terrestrial animal diseases diagnostic kits validated and certified by WOAH

CONSIDERING THAT

- 1. During the 71st General Session of WOAH in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by WOAH, and giving a mandate to the Director General to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic kit is taken by the World Assembly of Delegates,
- 2. The Resolution has established that "fitness for purpose" should be used as a criterion for validation,
- 3. The aim of WOAH's procedure for registration of diagnostic kits is to establish a register of recognised kits for WOAH Members and for diagnostic kit manufacturers,
- 4. WOAH Members need kits that are known to be validated according to WOAH standards in order to enhance confidence in kits,
- 5. WOAH's register of recognised diagnostic kits provides greater transparency and clarity of the validation process and a means for recognising those manufacturers that validate and certify tests marketed in kit format,
- 6. According to WOAH Standard Operating Procedure, registration of diagnostic kits included in the Register has to be renewed every 5 years,
- 7. During the 74th General Session in May 2006, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing WOAH standards for the validation and registration of diagnostic assays by Members,
- 8. The Validation Studies Abstracts are available as annexes to the report of the Biological Standards Commission of 6-9 February 2023 (for the VDRG® FMDV 3Diff/PAN Ag Rapid kit, Enferplex Bovine TB antibody test (additional claim), BOVIGAM® Mycobacterium bovis Gamma interferon test kit for cattle (extension of the claim), and Rapid MERS-CoV Ag Test (renewal with new studies). There is no Validation Studies Abstract for Mycobacterium bovis Antibody Test Kit, as this is a renewal without any additional data evaluation or changes.

THE ASSEMBLY

DECIDES THAT

1. In accordance with WOAH's procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes the inclusion in WOAH's Register of the following new terrestrial diagnostic kit certified by WOAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
VDRG® FMDV 3Diff/PAN Ag Rapid kit	MEDIAN Diagnostics Inc	The VDRG® FMDV 3Diff/PAN Ag Rapid kit is a lateral flow test or pen-side test intended for the universal detection of foot- and-mouth disease virus (FMDV) of serotypes A, O and Asia-1 in tissue samples (epithelium) or fluid from blisters or ruptured lesions of suspected swine or cattle. The test is designed to be used for the rapid diagnosis of foot-and-mouth disease virus infection in samples from swine or cattle.

2. In accordance with WOAH procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes to **amend WOAH validation of certification and fitness for purpose** in WOAH's Register of the following diagnostic kits certified by WOAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
Enferplex Bovine TB antibody test	Enfer Scientific ULC	Additional claim: Fit for the detection of antibody to <i>Mycobacterium bovis</i> in bovine milk samples (May 2023) to be used as an ancillary test in conjunction with other methods for serological prevalence surveys, or diagnosis and management of <i>M. bovis</i> infection
		 within herds, in particular for the following purposes: 1. To confirm, but not negate, diagnosis of suspect or clinical cases, including confirmation of positive screening tests in individual animals and in herds based on detection of antibodies in individual bovine milk samples excluding colostrum and first milk samples taken within 4 days of calving.
		2. As a screening test to identify herds with <i>Mycobacterium bovis</i> infection based on detection of antibodies in bovine bulk tank milk samples excluding colostrum and first milk samples taken within 4 days of calving.
		** In 2019 this test was provisionally approved for testing milk samples from cattle as a herd screening test or as a supplemental confirmatory test for use in individual animals, when used in conjunction with other methods for diagnosing and managing M . bovis infection (Resolution No.31)
BOVIGAM® Mycobacterium <i>bovis</i> Gamma interferon test kit for cattle	Prionics Lelystad B.V.	Extension of the claim The BOVIGAM® - $Mycobacterium$ bovis Gamma interferon test kit is an indirect assay intended for the detection of interferon- gamma (IFN _Y) response elicited to specific stimulation by M . bovis specific peptides or proteins, in plasma obtained from stimulated blood samples of suspected water buffalos (Bubalus bubalis).
		** The original registration with Resolution No. 34 was adopted by the World Assembly of the OIE/WOAH Delegates in 2015. This test was renewed (Resolution No.20) without any additional data evaluation or changes in 2020

3. In accordance with WOAH procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes **to renew** for a period of five additional years the inclusion in the WOAH's Register of the following diagnostic kit certified by WOAH as validated as fit for purpose:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
BIONOTE® Rapid MERS-CoV Ag Test Kit	BioNote, Inc	Certified by WOAH fit for the qualitative detection of Middle East Respiratory Syndrome Coronavirus antigens from nasal swabs in dromedary camels in the laboratory for the following purposes:
		- Detection of MERS CoV infected herds (herd test) with acutely infected animals with high virus loads;
		- When used as a supplemental test, to estimate prevalence of infection to facilitate risk analysis, e.g. surveys, herd health schemes and disease control programs
		**The original registration Resolution No.15 was adopted in May 2016 by the World Assembly of the OIE/WOAH Delegates
<i>Mycobacterium bovis</i> Antibody Test Kit	IDEXX Laboratories	Certified by WOAH as fit for the detection of antibodies to M . bovis in cattle serum and plasma samples, to be used as a supplemental test, in conjunction with other methods, for diagnosing and managing M . bovis infection.
		The test also has utility when performing sero- surveys to understand prevalence and risk of <i>M. bovis</i> infection at a herd management level.
		**The original Resolution No. 24 was adopted in May 2012 and renewed by the World Assembly of the OIE/WOAH Delegates by Resolution No. 19 in 2017

Register of aquatic animal disease diagnostic kits validated and certified by WOAH

CONSIDERING THAT

- 1. During the 71st General Session of WOAH in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by WOAH, and giving a mandate to the Director General to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic kit is taken by the World Assembly of Delegates,
- 2. The Resolution has established that "fitness for purpose" should be used as a criterion for validation,
- 3. The aim of WOAH's procedure for registration of diagnostic kits is to establish a register of recognised kits for WOAH Members and for diagnostic kit manufacturers,
- 4. WOAH Members need kits that are known to be validated according to WOAH standards in order to enhance confidence in kits,
- 5. WOAH's register of recognised diagnostic kits provides greater transparency and clarity of the validation process, and means for recognising those manufacturers that validate and certify tests marketed in kit format,
- 6. According to WOAH Standard Operating Procedure, registration of diagnostic kits included in the Register has to be renewed every 5 years,
- 7. During the 74th General Session in May 2006, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing WOAH standards for the validation and registration of diagnostic assays by Members,
- 8. The *Validation Studies Abstract* is available as annex to the report of WOAH's Aquatic Animal Health Standards Commission meeting of 15-22 February 2023 for the Innocreate Bioscience WSSV RP Rapid Test Kit for White Spot Syndrome Virus (WSSV) infection in shrimp.

THE ASSEMBLY

DECIDES THAT

1. In accordance with WOAH's procedure for registration of diagnostic kits and the recommendations of the Aquatic Animal Health Standards Commission, the Director General proposes the inclusion in WOAH's Register of the following new aquatic diagnostic kit certified by WOAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose	
Innocreate Bioscience WSSV RP Rapid Test Kit	Innocreate Bioscience Co., Ltd.	The Innocreate Bioscience WSSV RP Rapid Test Kit is qualitative detection kit for WSSV infection in shrimp. T lateral flow immunoassay device is designed for the followi purposes:	
		1. Field based confirmatory diagnosis of clinical cases (includes confirmation of suspect cases and a positive screening test)	
		2. Estimate the prevalence of infection to facilitate risk analysis in production system shrimp farms to aid in management practices. (The test kit should not be used to estimate prevalence in broodstock or post larvae shrimp for risk analysis prior to translocation to other farms or across borders).	
		3. For use in conjunction with other tests or diagnostic procedures as an aid in the diagnosis or other clinical or epidemiological assessments.	