

**Preventing and controlling zoonotic spill-overs:
Substantive elements for a WHO international agreement
on pandemic prevention, preparedness and response**

Discussion Note

Overall disclaimer:

This paper has been prepared by the services of the European Commission on the basis of initial internal discussions as well as in consultation with numerous experts. **The paper does not purport to be an exhaustive or comprehensive review of the complex issues covered therein.** It is only intended to contribute to the debate in the context of the deliberations of the Intergovernmental Negotiating Body (INB).

The paper should not be regarded in any way as a negotiating position. The paper and its content are entirely without prejudice to any future proposal. The illustrative provisions included in the paper are only aimed at exemplifying how provisions could look like. This does not imply that such provisions should be taken up for consideration in the upcoming negotiations.

The risk of zoonotic spillovers triggering major international outbreaks of infectious diseases in humans is an undeniable reality, as shown by regular and increasing health emergencies ranging from HIV-AIDS and pandemic influenza to COVID-19. This risk originates both from wildlife and livestock and carries with it the additional possibility of spillover of pathogens untreatable with known antimicrobials. The political momentum for dealing with this open problem from a regulatory perspective is confirmed by the numerous and consistent requests to include this topic as a priority in the future international agreement on pandemic prevention and response (“pandemic agreement”, PA).

This paper aims to further develop the elements included in section 1.b) of the EU contribution made to the INB on 29 April 2022 (see excerpt in Annex).

I. Justification for inclusion in the pandemic agreement

One Health was recently defined by the One Health High-Level Expert Panel as follows:

One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems.

It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe

and nutritious food, taking action on climate change, and contributing to sustainable development.

That definition underlines the intrinsic complexity and intersectoral nature of One Health and the need for an integrated scientific and regulatory approach, which has not been earnestly pursued so far, despite the increasing concern and mobilization of the communities most concerned. The international organizations dealing with the various aspects of One Health (WHO, FAO, WOAHA and UNEP, the so-called “Quadripartite”) have strengthened their cooperation since 2010, but their normative activities have been to a significant extent uncoordinated and based on “soft” technical instruments and modalities.¹

Even though much will depend on the eventual pandemic agreement’s scope, content and level of detail, as well as its relationship with other international regimes and institutions, the rationale for including One Health as a cross-cutting theme and one of the building blocks of the pandemic agreement and to focus specifically on preventing and controlling zoonotic spillovers can be summarized as follows:

- a. There is a lack of common understanding of the One Health approach. By including the One Health definition developed by the One Health High-Level Expert Panel in the pandemic agreement, a common understanding of One Health can be promoted.
- b. There is a gap in the international legal framework concerning the reduction of the risk of zoonotic spillovers that needs to be urgently filled to reduce the possibility of another devastating pandemic of a zoonotic disease. This shared awareness, and the political momentum to address at least the most urgent problems for the protection of human health, points to the negotiation of a pandemic agreement of broad scope as a unique opportunity.
- c. There is a vacuum in international law with regard to many aspects related to the prevention of zoonotic spillovers that requires a binding legal instrument as the most effective normative approach. That gap is situated between the regulation of structural environmental drivers of the animal-human interface, such as climate change, biodiversity loss and desertification, and the detection of a specific outbreak once it has occurred. The International Health Regulations (IHR), in particular, do not address the prevention of zoonotic spillovers and focus on detection and containment of an outbreak of a human disease after it has occurred. Other treaties (mostly multilateral environmental agreements (MEAs)) address issues, such as the conservation of biological diversity or climate change that stop “upstream” of the risk of zoonotic spillover and do not focus on the interactions between animals and humans.
- d. An effective and strategically designed international regulation of the “midstream prevention” of zoonotic spillover² would fill the existing gap in the international legal framework and complement international instruments that operate at an upstream or downstream level. The need for clear legal relations among international legal instruments points to binding disciplines as the preferable choice.

¹ There has been for instance regular coordination between the Codex Alimentarius and WOAHA with respect to AMR and other food safety related international standards developed by both, e.g. through systematic participation in each other’s expert groups.

² See Jorge Vinales, Suerie Moon, Ginevra Le Moli, Gian-Luca Burci, A global pandemic treaty should aim for deep prevention, *The Lancet*, 2021, available at : [A global pandemic treaty should aim for deep prevention - The Lancet](#).

- e. Binding provisions on preventing and controlling zoonotic spill-overs would facilitate the establishment of a better performing system for their prevention and early detection and constitute a major step forward for the prevention of future pandemics of zoonotic diseases. Such provisions would establish a One-Health integrated approach in data collection, analysis and sharing, rationalize and complement existing international mechanisms and initiatives, such as GLEWS+³, and build a dedicated and much needed science-policy interface for One Health.
- f. The need to bring together and ensure coordination and cooperation among diverse interests and concerned international institutions (WHO, FAO, WOAAH, UNEP as well as the secretariats of the MEAs) working on various aspects of the One Health interface will be a systemic challenge given their different memberships and sometimes different priorities. A binding instrument best embodies the political commitment and provides the legal clarity to organize such cooperation and coordination. It can create an institutional framework building on existing experiences to facilitate consultation, coordination and division of labour among existing regimes and institutions and prevent further fragmentation, including, e.g. through a coordinating mechanism bringing together the relevant international agencies (especially the Quadripartite organizations), thus creating the space for coordination and joint programming without modifying the mandate of the institutions concerned. In addition, existing efforts aimed at bridging WHO and WOAAH “core capacity” development tools on zoonoses and other One Health topics⁴ should be enhanced and institutionalized.
- g. The issues at stake and their regulatory needs emphasize the importance of building mutual trust and accountability as part of the design of the new instrument and its implementation, with a view to ensuring that all parties contribute to the common objectives and collective efforts. All this requires a balancing of incentives and deterrents that would secure sustainable commitments and compliance through accountability and support mechanisms.
- h. It should be stressed that a “binding agreement” does not imply that the latter should be highly prescriptive and detailed in all areas. The actual design of the instrument should be adapted to its functions, to the desired regulatory goals and to what is realistic from a political and practical point of view. Contemporary treaty practice, in particular the diffusion of the framework convention model in the environmental field, as well as the hard/soft combination of provisions, such as in the Paris Agreement on climate change, offer a range of precedents in this connection.

II. Relations with applicable WHO norms or policies, as well as IHR (2005), and other international instruments

As noted above, the IHR focus on detection and containment of outbreaks of diseases in humans. They address prevention only to a very limited extent through the provisions on “core capacities”, and they do not incorporate a One Health perspective or cover animal diseases or environmental factors. At the same time, the guidance and assessment tools developed by the WHO secretariat for IHR implementation, in particular the Joint External Evaluation and the State Party Self-Assessment Annual Reporting Tool, include specific goals and indicators on

³ <http://www.glews.net/>

⁴ For instance, the national IHR-PVS bridging workshops, see <https://extranet.who.int/sph/ihr-pvs-bridging-workshop>.

zoonotic events and the human-animal interface. A future pandemic agreement incorporating a One Health approach, and the prevention and control of zoonotic spill-overs in particular, will need to complement the IHR and build on the experience gained on zoonotic events through its implementation.

In addition, prevention and control of zoonotic spillovers will by necessity have to address the prevention of infections by pathogens untreatable with known antimicrobials. Negotiations will thus have to ensure consistency with existing WHO and WOAAH instruments, in particular the 2015 WHO Global Action Plan on antimicrobial resistance, as well as with instruments adopted within the UNEP. The One Health Joint Plan of Action, as recently launched by the Quadripartite, should also provide guidance during the negotiations of the pandemic agreement.

Given the complexity and broad scope of One Health, with particular regard to the environmental drivers of zoonotic risks, a number of MEAs are relevant for a holistic approach to One Health that fully takes into account its environmental dimension. Even though the One Health component of a future pandemic agreement should fill the normative gap left by those treaties for reducing the risk of zoonotic spillovers, normative and institutional complementarity and synergy will be necessary to ensure coherence in rules- and policy-setting. This should include consultation and cooperation with the secretariats of the treaties in question. The main instruments referred to here include:

- The United Nations Framework Convention on Climate Change;
- The Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity;
- The United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa;
- The Protocol on Water and Health to the Convention on the Protection and Use of Transboundary Watercourses and International Lakes.

Other international agreements that will have to be taken into account for the purpose of coherence and consistency include the WTO SPS Agreement, as well as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). These agreements may facilitate prevention of zoonotic spillovers through international trade in animals, plants and foodstuff. However, CITES is a conservation instrument and does not extend to an assessment of the health risks of wildlife trade. In this connection, ensuring the rapid international shipment of biological samples of protected wild animals for purposes of zoonotic disease diagnostics can in some cases be difficult. Further considerations should be given to facilitating shipments of biological samples for emergency diagnostic purposes, with the view of enhancing the detection, prevention and response to zoonotic disease transmission.

Finally, the pandemic agreement - or subsequent instruments developed on its basis - will have to ensure consistency with the normative standards adopted by the WOAAH - in particular the Terrestrial Animal Health Code and the Aquatic Animal Health Code and its Manuals - to avoid fragmentation, duplication and uncertainty on the applicable normative standards. This consideration applies especially with regard to their provisions on surveillance, notification, biosecurity, disease prevention techniques and trade measures.

III. Possible provisions in the Pandemic Agreement

A One Health component of a future pandemic agreement will need to embody a holistic approach that transcends a purely anthropocentric perspective, build on existing policies, mandates and data, while being sensitive to the significant differences in national situations, needs and problems.

Without prejudice to further reflection and discussion within the INB and solely by way of examples, the pandemic agreement, including by way of voluntary guidelines or subsequent protocols, could contain the following types of measures, some of which may cut across the whole instrument rather than being specific to the issue of preventing and controlling zoonotic spill-overs:

- 1) Establishing an institutional mechanism for collection, aggregation, sharing and analysis of data on human and animal populations, environmental factors, pathogen and disease distribution, based on interoperable data information systems, as well as to provide the scientific input for policy-making;
- 2) National and regional commitments, reflecting diversity of national and local situation, to adopt and implement plans to map and reduce zoonotic risks emerging from animals (wildlife and livestock);
- 3) Developing national and regional core capacities to ensure integrated One Health surveillance and reporting. This aspect will have to be coordinated with the core capacities and reporting obligations under the IHR and WOAHA standards;
- 4) Due diligence obligations and health impact assessment for trade in animals posing particular risk, such as wild animals;
- 5) Adoption of international normative standards, where needed, as well as operational plans and guidance to provide benchmarks, targets and indicators for national and regional action, in close coordination with the international institutions concerned;
- 6) Promotion of environmental strategies aimed at restoring natural habitats, biodiversity and clean environments as a matter of urgency to protect the health of the environment, animals and humans, whilst deploying methods of surveillance of pathogens and antimicrobial resistance genes in the environment using environmental genomic methods;
- 7) Provision of dedicated technical assistance and capacity-building;
- 8) Establishment of an institutionalized mechanism for accountability and compliance monitoring, including field missions for assistance and verification, within the broader institutional framework of the future instrument.

The provisions below are offered in order to start a concrete discussion with partners and stakeholders.

Article A (Surveillance at the wildlife-livestock-human interface)

1. Each Party shall develop, strengthen and maintain the capacity to carry out integrated surveillance of infectious diseases in humans, of infectious diseases in animals presenting significant zoonotic risks, as well as of relevant environmental indicators, and samples taken from specific environmental settings, for the purpose of preventing and controlling the spillover of potentially dangerous pathogens between humans and animal populations, as well as between different animal species. Such surveillance shall encompass livestock, companion animals, high-risk wildlife, as well as vectors as defined by the Conference of the Parties.

Parties shall promptly communicate to the Secretariat⁵ new or updated data and information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international organizations.

2. Parties shall cooperate with one another in bilateral, regional and multilateral settings in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of low and lower middle-income countries which are Parties to the Agreement. Parties shall coordinate surveillance activities as appropriate taking into account the decisions of the Conference of the Parties and the recommendations of relevant international organizations and facilities.

3. The Conference of the Parties shall adopt recommendations on the harmonization and standardization of information and data arising out of their surveillance activities to ensure the interoperability of data information systems and the comparability and integration of information and data for the purpose of an effective assessment of national, regional and international risks of zoonotic diseases.

4. Parties to the United Nations Framework Convention on Climate Change, the Convention on Biological Diversity, the United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, the Protocol on Water and Health to the Convention on the Protection and Use of Transboundary Watercourses and International Lakes that are also Parties to the present Agreement shall interpret and implement those instruments so as to ensure consistency and complementarity with the present Agreement and to strengthen its effective implementation.

Article B (Pathogen surveillance and identification)

1. Each Party shall develop, strengthen and maintain the capacity to detect, identify and characterize in areas within its jurisdiction pathogens presenting significant zoonotic risks and to assess as much as possible their likelihood to cause community spread and serious diseases.

2. Without prejudice to existing reporting and notification obligations, each Party shall promptly inform the Secretariat about the pathogens referred to in paragraph 1 that it has detected, and communicate the information and data on their characteristics that it has been able to assemble. The Party shall promptly communicate to the Secretariat new or updated data and information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international organizations.

3. Parties shall cooperate with one another in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of low and lower middle income countries which are Parties to the Agreement, especially with respect to the capacity to perform genetic sequencing of detected pathogens and safely handle samples containing pathogens. They shall promote and facilitate the provision of necessary assistance by relevant international organizations.

⁵ The institutional provisions of the PA will determine the arrangements to ensure the Secretariat functions. The WHO could provide Secretariat support to the PA. Different arrangements involving joint secretariat functions bringing together different international organisations, especially the Quadripartite organizations could be also envisaged in specific policy areas, especially when linked to One Health.

Article C (Control of illicit wildlife traffic)

- 1. Subject to their international obligations, Parties shall adopt legislative, administrative and technical measures to ensure safe legal trade and prohibit and prevent the illicit national and international trade of animal and plant species especially those that may pose a higher risk of zoonotic diseases based on the result of their surveillance under Articles A (Surveillance at the wildlife-livestock-human interface) and B (Pathogen surveillance and identification).*
- 2. Parties shall, before authorizing the export or import of wildlife specimens, assess the risk to human and animal health deriving from pathogens generally or likely hosted by the species to which the specimens in question belong, or from laboratory testing of the specimens. They shall not allow or, as the case may be, subject the authorization to specific risk mitigation measures to prevent or reduce the risk of spread of disease into human or other animal populations. Parties shall facilitate the rapid export of biological samples of wild animals for purposes of zoonotic disease diagnostics.*
- 3. Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora that are also Parties to the present Agreement should integrate the assessment required under paragraph 2 in their regulation of trade under that Convention.*

Article D (Sharing of pathogen samples, genetic sequences and equitable sharing of benefits)

- 1. With a view to fostering international cooperation and coordination in the surveillance and control of pathogens presenting significant zoonotic risks and without prejudice to their obligations under paragraph 3 of Article B (Pathogen surveillance and identification), Parties shall endeavour to exchange either directly or through the Secretariat or other existing mechanisms genetic sequences of pathogens detected through their surveillance activities. Parties may seek the cooperation of other Parties with more advanced technological capacities in order to fully identify and characterize the pathogens in question. The Conference of the Parties shall as soon as possible after the entry into force of this Agreement adopt modalities to facilitate and support the exchange and storage of pathogens, as well as the exchange of genetic sequences of pathogens, in accordance with international law.*
- 2. Parties shall endeavour to equitably share the relevant medical countermeasures produced with the assistance of pathogens and genetic resources shared in accordance with paragraph 1. The Conference of the Parties shall as soon as possible after the entry into force of this Agreement adopt modalities to facilitate and support the equitable sharing of such relevant countermeasures.*
- 3. The Conference of the Parties shall consider the establishment of an international repository of pathogen samples and genetic sequences falling under the present Agreement. This may include the utilization of existing national, regional or international repositories on the basis of agreements concluded with the States concerned. Repositories shall be accessible to Parties on an equitable and transparent basis and without discrimination. They shall be accessible to non-Parties on conditions to be decided by the Conference of the Parties. Data repositories shall comply with global norms and standards established by WHO, such as the WHO Principles of Pathogen Genome Data Sharing.*

Article E (Training)

Parties shall promote, establish or enhance joint training programmes between, and continuing education of, human, animal and environmental health professionals and the inclusion of the One Health approach in health studies.

Article F (Scientific and technological advice)⁶

1. *An expert body to provide scientific and technological advice, building upon the work of the One Health High-Level Expert Panel, is hereby established to provide the Conference of the Parties and Parties to this Agreement with information and advice on scientific and technological matters relating to the Agreement. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work. The body shall:*

- a) Provide or compile assessments of the state of scientific knowledge relating to zoonotic risks from a One Health perspective;*
- b) Prepare scientific assessments on the effects of measures taken in the implementation of the Agreement;*
- c) Provide advice as appropriate on scientific programmes, international cooperation in research and development related to matters covered by the Agreement, as well as on ways and means of supporting endogenous capacity building in low and lower-middle income countries, as well as other middle income countries in need; and*
- d) Respond to scientific, technological and methodological questions that the Conference of the Parties may put to the body.*

2. *The Conference of the Parties shall define the working methods and precise terms of reference of the body. It shall ensure that the body includes a mechanism, composed of individual experts not representing Parties, for the review, analysis and summary of available scientific information and data about zoonotic risks using a One Health approach. The Conference of the Parties shall invite relevant international organizations and other stakeholders to participate in the expert body and shall ensure that the body draws upon their expertise.*

Article G (International standards and national measures)

1. *The Conference of the Parties shall, on the basis of the findings and advice of the expert body for scientific and technological advice as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, adopt guidelines, recommendations, standards and other instruments, as necessary, to guide and support Parties in the adoption of national measures aimed at the implementation of this Part and more generally to the reduction of zoonotic risks in a One Health Perspective.*

2. *Parties shall, in accordance with their international obligations, adopt policies and measures of a legislative, regulatory, administrative and technical nature for the purpose of:*

- a) Identification and mapping of geographical areas, animal and plant species, activities and practices within their jurisdiction which may require particular surveillance;*
- b) Monitoring environmental factors associated with the risk of zoonotic diseases, such as water-borne pathogens and diseases, water quality, unsustainable land uses or deforestation;*
- c) On the basis of their activities under sub-paragraphs a) and b), reducing as much as*

⁶ This article could also be included in the part setting out the institutional provisions of the PA.

possible the risk of zoonotic diseases by controlling and adapting relevant activities and practices, such as certain unsustainable land uses and wildlife consumption practices;

- d) Adapting farming practices, including within the context of large-scale animal farming, with a view to preventing the insurgence of antimicrobial resistant pathogens;*
- e) Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets selling live wildlife;*
- f) Developing, strengthening and maintaining animal welfare policies and practices to ensure the humane and adequate treatment of wildlife, farm and companion animals at all stages of their trading, rearing, transport and slaughter, as well as to improve hygiene and reduce long distance transportation of live animals.*
- g) Monitoring the effectiveness of the adopted policies and measures for the purpose of constantly strengthening them and increasing their effectiveness.*

3. Without prejudice to existing obligations Parties should base the policies and measures established under this Article on the recommendations, guidelines and standards adopted by the expert body for scientific and technological advice provided for in Article F, as well as by relevant international organizations and bodies, with particular regard to WHO, WOAH and the Codex Alimentarius Commission.

4. Parties shall fully take into account the rights, needs and traditional practices of indigenous and local communities in order to avoid creating discrimination and depriving such communities of their livelihood and traditional knowledge. Parties shall consult and involve indigenous and local communities in the elaboration and implementation of the measures referred to in this Article.

5. Each Party shall report on the measures adopted and implemented under this Article to the Conference of the Parties every [...] years after the entry into force of the Agreement for that Party. The Conference of the Parties shall specify the information required from Parties, with particular regard to the challenges encountered and assistance needs. The reports will be examined by [mention the compliance assessment mechanism established by the Agreement] for the purpose of identifying general problems requiring action by the Conference of the Parties and of encouraging Parties to constantly improve their policies and practices.

6. Each Party shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing measures under this Article, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building especially in low and lower-middle income countries, as well as other middle income countries in need.

Annex: Excerpts from section 1.b) of the European Union contribution to the identification of the substantive elements for a convention, agreement or other international instrument on pandemic prevention, preparedness and response, as submitted to the INB on 29 April 2022

1. Preventing and controlling public health threats with pandemic potential

(...)

b) Preventing and controlling zoonotic spill-overs through:

16. *Enhancing and harmonising surveillance and notification systems at the wildlife-livestock-human interface (in line with the One Health approach) and enabling the timely flow of information through interoperable surveillance and risk assessment systems between human health, animal health and environmental authorities at local, regional and international levels (including by supporting the WHO Hub for Pandemic and Epidemic Intelligence). The PA provisions should be complementary to existing IHR and World Organisation of Animal Health (OIE) provisions.*

17. *Regulation of wild and live domestic animal markets and stricter surveillance and control of illicit wildlife traffic and wet markets, both domestically and internationally.*

18. *Pathogen surveillance and identification of emerging and re-emerging pathogens with a high zoonotic infection potential (including through the early warning and alert system described in section a) above and the improvement and interconnection of databases) in livestock, companion animals and high-risk wildlife populations and vectors. This should build on the work of the Scientific Advisory Group for the Origins of Novel Pathogens (SAGO), while mindful of remaining consistent and avoiding duplications with the OIE mandate.*

19. *Systematic exchange of information and data on pathogens, variants and genetic sequencing at the animal-human interface with standardized and harmonized data.*

20. *Universally accessible sample collection capacities (repositories) and equitable pathogen sample sharing, also by connecting and standardizing existing sharing platforms, while respecting biosecurity and biosafety requirements.*

21. *Developing protocols and recommendations for voluntary sharing of scientific findings, surveillance and diagnostic data, research results and samples, including through the contributions of the WHO Hub for Pandemic and Epidemic Intelligence.*

22. *Increasing knowledge and capacity to prevent and address risks from zoonoses and other public health threats at the human-animal-ecosystem interface, notably due to the loss of natural habitats and decreasing biodiversity or other factors, in line with the “One Health” approach and taking into account the work of the OHHLEP.*

23. *Promoting environmental protection actions aimed at significantly reducing the risk of zoonotic spill-overs.*

24. *Enhancing joint trainings between, and continuing education of, human and animal health professionals and the inclusion of the One Health approach in health studies.*