

Module Jean Monnet PROHTECT Promoting operationalisation of One Health Through EU Juridical Tool

One Health Policy Legal Clinic: Protecting Health Beyond National and
Disciplinary Boundaries

20 marzo 2025

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I part



PROHTECT



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Promoting operationalisation of One Health Through EU juridical Tool

The Effects of Globalization on the Right to Health

- *Focus* on infectious diseases and the international and European instruments for their management.

Health in the Age of the Anthropocene

- Epoch, period, or geological era characterized by exponential growth (the so-called 'Great Acceleration' of 1945) and by territorial, structural, and climatic changes brought about by human activity on geological processes.

Globalization and health



INTERNATIONAL FLIGHTS

1960: 70 million

2004: 760 million

Negative effects:

- Human mobility = virus mobility
- Enhancement of international transportation, growth of tourism, market liberalization → intensification of commercial traffic
- Eating habits
- Intensive farming (threat to biodiversity)
- Meat consumption (intensive livestock farming—movement of live or slaughtered animals)

Globalization and health



Positive effects:

- Spread of well-being
- New opportunities
- Circulation of healthcare
- Development of international cooperation in health matters

Global Health Governance

Transnational Health Threats -> Forms of Transnational Collaboration

- Proliferation of non-state actors (no governments, but global governance);
- Fluidity of areas of competence due to the impact of non-health factors on health
- Fluidity of hierarchies
- Prevalence of coordination and cooperation tools

Limits:

- Tendency toward conflict rather than cooperation
 - "Variable geometry" participation in supranational organizations
 - Dominance of interests from powerful states
 - Non-coercive nature of obligations assumed at the international level
-
- **1970:** Economic growth + disparities (the so-called Third World) also in terms of health (e.g., maternal mortality)
 - **1989:** End of the Cold War -> intensification of international cooperation, including in health matters
 - **NB:** Proliferation of intergovernmental organizations = competition for resources and leadership



World Health Organization (WHO)

Established in 1946-1948 as a United Nations Agency

- Absorbs the competencies of pre-existing organizations (Office International d'Hygiene Publique, League of Nations, etc.)
- Based on a universal vision of health and well-being
- Asserts the "fundamental" nature of the right to health
- Each country is a member (61 countries in 1946 - 194 countries in 2014) and holds one vote in the World Health Assembly
- Development of international guidelines and coordination of global disease-fighting campaigns
 - Example of success: Smallpox 1966-1980
 - Example of failure: HIV-AIDS 1980-1990



International Sanitary Regulations (WHO)

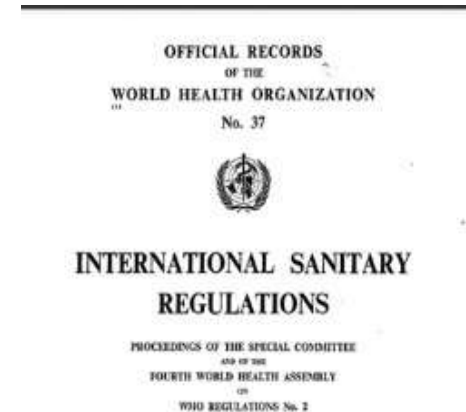
1951

- Unifies the international conventions signed by public health protection institutions developed since the late 1800s.
- Obligates countries to notify the emergence of a "quarantinable" disease; provide information on the source, type of disease, infected cases and deaths, and measures of prophylaxis taken; establish public health structures at key entry/exit points of the country (e.g., ports).

Many subsequent versions, with few substantial changes (updating the list of "quarantinable" diseases).

Shortcomings:

- Quarantine only for confirmed cases (does not account for the incubation period).
- Low adherence to the notification obligation (fears of economic losses, tourism).
- Focus on known diseases (does not address emerging infectious diseases).

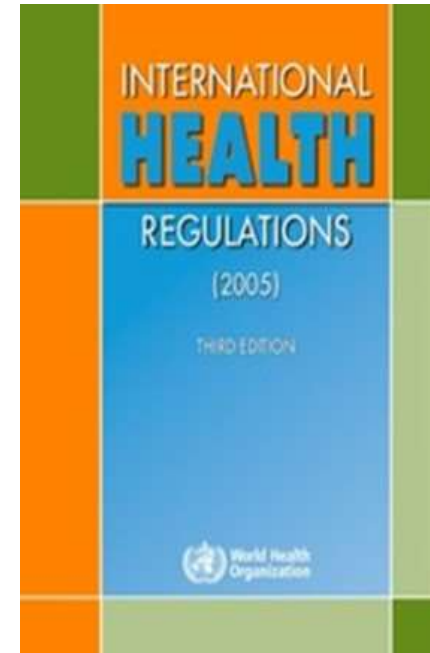


Health Crises: SARS; Bovine Spongiform Encephalopathy; Avian Influenza H5N1:

- Urgency to focus on emerging infectious diseases.
- Last edition in 2005 (negotiations began in 1995, conclusions accelerated by the SARS epidemic of 2002-2003).

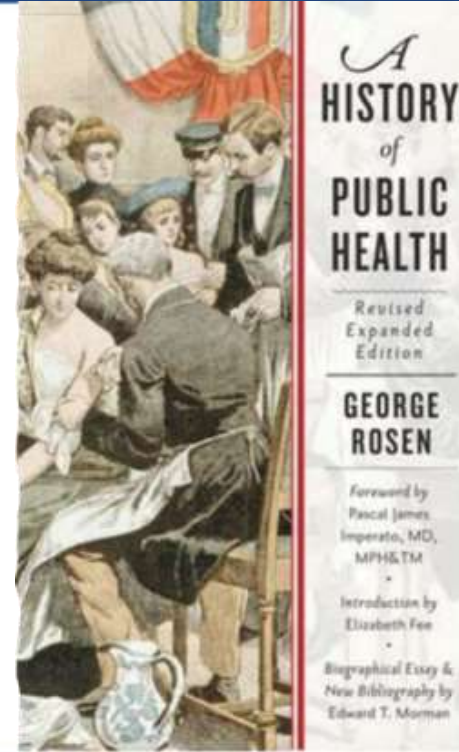
Key changes:

- Eliminates the static list of diseases.
- No state monopoly on notification.
- Introduces the urgency of public health threats of international concern (Note: not declared in the early stages of COVID-19).
- Organizes collaboration between "contact points" and "national focal points."
- Puts an obligation on the signatory states to enhance their capacity for prevention and response to public health emergencies of international concern.



What role for the EU in global health governance?

- European healthcare systems share a common core, consisting of welfare systems formed after World War II and progressively reformed in the 1990s.
- Despite their respective differences, each state plays a predominant role in its own health policies.
- EU member states have always been very reluctant to transfer additional powers in the field of health to the community level. However, they have done so when forced by a common crisis that could not be addressed independently by a single country.



History

Treaty of Rome, March 25, 1957 (EEC)

- Aims to integrate markets (NO harmonization of social systems).
- Considers health as a matter within the exclusive domain of Member States.
- It is an exception that can be invoked by Member States to limit the free movement of goods within the market, leaving "unaffected the prohibitions or restrictions on the import, export, or transit" of goods (former Article 36 of the EEC Treaty).



European Social Charter

On October 18, 1961, the **Council of Europe** established rights that were developed outside the EU legal framework, which later became general principles common to the legal systems of the Member States in the case law of the **CJEU**.

Article 11 – Right to Protection of Health

To ensure the effective exercise of the right to protection of health, the Parties undertake to adopt, both directly and in cooperation with public and private organizations, appropriate measures aimed in particular at:

- eliminating, as far as possible, the causes of ill-health;
- providing advisory and educational facilities concerning the improvement of health and the development of individual responsibility in matters of health;
- preventing, as far as possible, epidemic, endemic and other diseases, as well as accidents.

Article 13 – The Right to Social and Medical Assistance

With a view to ensuring the effective exercise of the right to social and medical assistance,

- the Parties undertake: to ensure that persons who are without adequate resources and who are unable to secure such resources either by their own efforts or from other sources, in particular by benefits under a social security scheme, be granted adequate assistance, and, in case of need, to take other measures necessary to improve their condition; to ensure that persons who are without adequate resources and who are unable to secure such resources either by their own efforts or from other sources, in particular by benefits under a social security scheme, be granted adequate assistance, and, in case of need, to take other measures necessary to improve their condition;
- the reduction of political or social rights by reason of birth, race, sex, language, religion, political opinions, or other opinions, or by reason of which, using any methods of social work, would contribute to the welfare and development of both individuals and groups in the community; to apply to and to their adjustment to the social conditions of the territory, the provisions of paragraphs 1 and 2, in particular, to nationals of other Parties lawfully within their territories, in accordance with their obligations under the European Convention on Social and Medical Assistance, signed at Paris on 11 December 1953.

Health in EC/EU Treaties

T. Rome (1957)	EC Institutions (liberal optimism)
Single European Act (1986)	Policy of economic and social cohesion: to be implemented by the States with European Social Funds (Structural Funds). Work-oriented
T. Maastricht (1992)	Enhancement of EU competences on WORK Article 129: The need for health protection is explicitly recognized in the text of the treaty, which affirms its cross-cutting nature, as it is a constituent component of the other policies of the Community.
T. Amsterdam (1997)	Article 129 becomes 152 with a change that is not just nominal. It includes, among the areas of cooperation between Member States, diseases and major epidemics, as well as, in general, all causes of danger to human health, with the overall objective of improving public health.
CFREU (2000)	Reference to fundamental social rights enshrined in the EUROPEAN SOCIAL CHARTER It equates freedom rights and social rights (inviolability of human dignity, right to form a family, right to work, etc.), including the right to HEALTH, which encompasses access to preventive healthcare and medical treatment (Title IV - Solidarity). However, it does not guarantee a healthy life, which is subject to 'conditions established by national legislation and practices' (Article 35, see below). Note: 'recognizes and respects' Note Article 51(2) -> does not introduce new competences or tasks; Note Article 52: 'the provisions of this Charter that contain principles MAY be implemented by legislative and executive acts of EU bodies or Member States.
T. Lisbon (2009)	Article 2 TUE: The EU promotes economic and social progress for balanced and sustainable development. Article 2(5) TFEU: To support, coordinate, or complement the actions of Member States, without, however, substituting their competence in these areas. Article 4(k) TFEU: Shared competence on "common security issues in public health matters, as defined in this treaty." Article 6 TFEU: Complementary and coordinating competence "for the protection and

Article 35 of the Charter of Fundamental Rights of the European Union (CDFUE)

Article 35 - Health Protection

Everyone has the right of access to preventive health care and to benefit from medical treatment under the conditions established by national laws and practices. In defining and implementing all Union policies and activities, a high level of human health protection shall be ensured.

Article 168 TFEU (formerly Article 152 TCE)

Ancillary role, coordination, completion, and support with respect to the Member States.

1. In the definition and implementation of all Union policies and activities, a high level of human health protection is guaranteed.

- The Union's action, which complements national policies, aims at improving public health, preventing diseases and conditions, and eliminating sources of danger to physical and mental health. This action includes the fight against major epidemics, promoting research on their causes, spread, and prevention, as well as health information and education, surveillance, alert systems, and fighting serious cross-border health threats.

The Union complements the actions of Member States aimed at reducing harmful effects on human health caused by drug use, including information and prevention.

2. The Union encourages cooperation among Member States in the areas covered by this article and, where necessary, supports their actions.

In particular, it encourages cooperation among Member States to improve the complementarity of their healthcare services in border regions.

- Member States coordinate their policies and programs in these areas with one another, in connection with the Commission. The Commission may take any useful initiatives to promote such coordination, particularly initiatives aimed at defining guidelines and indicators, organizing exchanges of best practices, and preparing elements necessary for regular monitoring and evaluation. The European Parliament is fully informed.

3. The Union and Member States promote cooperation with third countries and relevant international organizations in the field of public health.

(Continued) Article 168 TFEU (formerly Article 152 TEC)

4. Notwithstanding Article 2(5) and Article 6(a), and in accordance with Article 4(2)(k), the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, contribute to achieving the objectives set out in this article by adopting, to address common security problems:

- a) measures setting high standards of quality and safety for human organs and substances, blood and blood products; these measures shall not prevent Member States from maintaining or introducing more stringent protective measures;
- b) measures in the veterinary and plant health sectors with the primary objective of protecting public health;
- c) measures setting high standards of quality and safety for medicines and medical devices.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures to protect and improve human health, particularly to fight against major epidemics spreading across borders, measures concerning surveillance, alert systems, and fighting serious cross-border health threats, and measures directly aimed at protecting public health with regard to tobacco and alcohol abuse, excluding any harmonization of national legislative and regulatory provisions of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.

7. The Union's action respects the responsibilities of the Member States in defining their health policies and organizing and delivering health and medical care services. The responsibilities of the Member States include the management of health services and medical care and the allocation of the resources dedicated to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation and medical use of organs and blood.

Health outside Treaties

The right to health has only recently been explicitly recognized in primary EU law sources, but ... the need for health protection has been contemplated in various provisions:

- **Since the founding treaties**, as an exception invoked by Member States to justify the introduction or maintenance of restrictions on the free movement of goods, the right of establishment, or the free provision of services (former Article 36 of the EEC Treaty).
- In the coordination instruments for social security rules for workers (1958 and 1971).
- As a tool to ensure a healthy working environment (starting from the Single European Act of 1986).
- As a means to facilitate the free provision of healthcare services, both in terms of the mobility of professionals (mutual recognition of medical qualifications, Directive 2005/36/EC) and access to care for patients (the EU jurisprudence led to the Directive on cross-border healthcare 2011/24/EU).
- In the event of incidents leading to public health emergencies.

Year	Health Risks Faced by Europe
1950s-1960s	Thalidomide crisis: sedative, anti-nausea, and hypnotic -> discovery of the harmful effects linked to a component of its molecular structure: women treated with thalidomide gave birth to infants with severe congenital limb development abnormalities.
1970	Dioxin crisis: a cloud of dioxin is released from the Icmesa cosmetics factory in Seveso.
1986	Mad cow crisis: Bovine Spongiform Encephalopathy (BSE) spreads.

Legislation in specific areas of exclusive competence, such as commercial agreements on goods and product trade authorizations:

- **Regulation of medicines** (starting from 1962 with patent laws and harmonization of market authorization from 2001-2004; from 1988, Directives on the transparency of drug pricing).
- Then also for **medical devices** (mutual recognition and standardization of requirements → specific regulation starting from the 1990s).
- **Common policy on preventing health damage** from industrial activities: Directive 82/501/EEC of the Council, 24 June 1982, the so-called "Seveso Directive" (now Directive 2012/18/EU, "Seveso III").
- **Food regulation** (as an agricultural product) in terms of health protection → **food labeling** for products intended for human consumption (e.g., 1962 Directive on the use of food colorants - food safety - which later led to the creation of a dedicated agency).
- **Ad hoc decisions** by the Commission in 1989, 1994, 1998 related to **epidemiological surveillance** of transmissible spongiform encephalopathies.



EU and epidemiological surveillance and control of infectious diseases

- Decision No. 1082/2013/EU of the European Parliament and Council of 22 October 2013 concerning serious cross-border health threats, which repeals Decision No. 2119/98/EC, established a network for epidemiological surveillance and control of communicable diseases.

Developments in the Prevention and Management of Health Risks in the Post-Pandemic Era

Three new regulations to strengthen the Union's response to cross-border health or epidemic emergencies:

- Regulation (EU) 2022/2370 of the European Parliament and Council of 23 November 2022, which substantially amends the European Centre for Disease Prevention and Control (ECDC) created in 2004.
- Regulation (EU) 2022/2371 of the European Parliament and Council of 23 November 2022 concerning serious cross-border health threats.
- Regulation (EU) 2022/2372 of the Council of 24 October 2022, which establishes a framework of measures to ensure the supply of medical countermeasures relevant to crises in the event of a public health emergency at the Union level.



Year	Health Risks Faced by Europe
...	...
2020	Covid-19 crisis

Reg (EU) 2020/521 14.4.2020: Emergency funding to finance, at the expense of the EU budget, the necessary expenses to tackle the pandemic for the period from 1 February 2020 to 31 January 2022.

Extraordinary Action Plan “EU Strategy for COVID-19

Vaccines”: Flexibility mechanisms in the existing regulatory framework to accelerate vaccine accessibility, along with direct negotiations with the manufacturing company for the purchase of doses of the only authorized drug at the time, with costs borne by the EU budget.

Racc (EU) 2020/1475, coordinated approach to restricting freedom of movement in response to the COVID-19 pandemic -> Reg (EU) 2021/953 of 14 June 2021 (EU Digital COVID Certificate).

Developments in Health Risk Prevention and Management at the EU Level in the Post-Pandemic Era

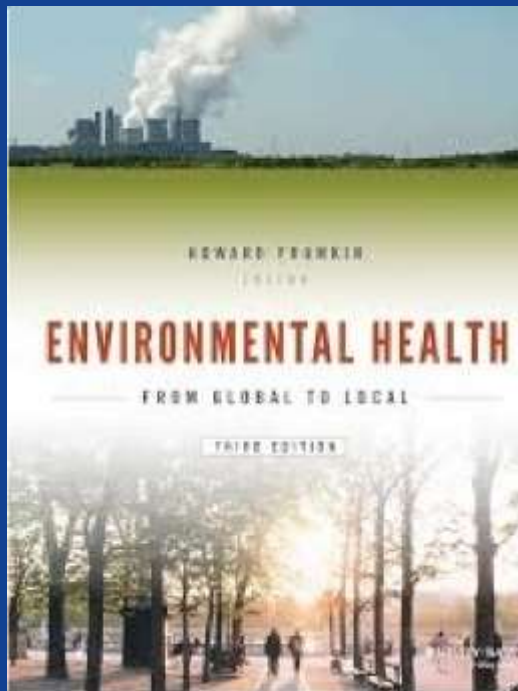
Three New Regulations Aimed at Strengthening the EU's Response to Cross-Border Health or Epidemic Emergencies

- **Regulation (EU) 2022/2370 of the European Parliament and of the Council, dated November 23, 2022:**
This regulation significantly amends the **European Centre for Disease Prevention and Control (ECDC)**, which was established in 2004. The revision aims to enhance the ECDC's capacity to monitor, assess, and respond to public health threats, improving the EU's ability to address emerging health risks and providing a more coordinated response to cross-border health emergencies.
- **Regulation (EU) 2022/2371 of the European Parliament and of the Council, dated November 23, 2022:**
This regulation focuses on **serious cross-border health threats**, establishing mechanisms for more coordinated surveillance, preparedness, and response across the EU member states. It aims to ensure better alignment and faster action during health crises, with particular attention to transnational threats such as pandemics, infectious disease outbreaks, and other public health emergencies.
- **Regulation (EU) 2022/2372 of the Council, dated October 24, 2022:**
This regulation creates a framework to ensure the **supply of medical countermeasures** of relevance during crises involving public health emergencies at the EU level. It aims to ensure the availability and rapid distribution of critical medical supplies, including vaccines, medicines, and diagnostics, during health emergencies, thereby strengthening the EU's ability to manage and mitigate the effects of public health crises.



Health and Enviromental

Health and Environment



Health and Environment:

Environmental Health: describes the direct pathological effects resulting from chemicals, radiation, and biological agents, as well as the (often indirect) effects on health and well-being caused by the physical, psychological, social, and aesthetic environment, including housing, urban development, land use, and transportation.

History:

History has always known measures to counteract the impact of environmental conditions on health (so-called public hygiene measures), such as:

- Food safety measures on how to preserve food (-> connections with dietary restrictions in ancient Jewish and Islamic law) and ensuring clean water and wastewater disposal.
- Studies in the late 1800s on industrial settlements and infectious diseases.
- 1960s studies on the absorption of DDT in the plant and animal worlds, with an increase in cancer and birth defects in humans.

The Phases of Environmental Legislation (Second Half of the 20th Century)



Risk of Polarization between Environment and Health = Reduced Attention to Environmental Health

- 1st wave: Conservative movement
2nd wave: 1970 (First Earth Day) Militant activism
3rd wave: 1980s - Proliferation of environmental organizations also connected with health
- 1989 European Charter on Environment and Health (WHO-Europe) acknowledges that "human health is dependent on a wide variety of environmental factors," emphasizes that "the prevention of health risks through environmental protection is vital," and recognizes that "a clean and harmonious environment has a beneficial influence on health and well-being."
- 1991: European Centre for Environment and Health (WHO-Europe)
- 1992: Earth Summit in Rio -> Rio Declaration ("Human beings are at the center of concerns for sustainable development. They have the right to a healthy and productive life in harmony with nature.
- 2003: Conclusions of the Council on October 27 on the European Strategy for Environment and Health
4th wave: Environmental justice (emphasis on human rights and distributive justice)

Environmental Changes and Health

- Increase in climate variability and extreme weather events (impact on infectious vectors)
- **Ozone:** greenhouse gases degrade ozone molecules in the stratosphere -> greater penetration of UV rays -> increased risk of skin cancer, cataracts, conjunctival cancer, weakened immune system
- **Ecosystem degradation:** reduced productive capacity of natural resources + ecosystem alterations due to invasive species
- **Biodiversity loss**
- **Water resource stress**



Climate Change and Health

- **Direct impacts:** changes in exposure to "thermal extremes" (heating and cooling); increase in extreme weather events (floods, cyclones, storms, droughts); increase in pollutants and allergic vectors (spores and molds).
- **Indirect impacts:** impact on food production; impact on the proliferation of infectious vectors (malaria and dengue -> mosquitoes, leishmaniasis -> sand fly).
- **Compensation:** milder winters reduce the peak of seasonal mortality, increased temperatures may hinder mosquito life in hot areas.
- **However**, in the vast majority of cases, the health effects of climate change are negative.



The 2022 report of the Lancet Countdown on health and climate change: health at the mercy of fossil fuels

- **Impact of Extreme Climate Events** -> Vulnerable populations are more exposed to heatwaves, leading to an exponential increase in heat-related deaths.
- **Impact of Rising Temperatures:** Coastal waters are more suitable for pathogen transmission (e.g., Vibrio). The number of months suitable for malaria transmission has increased by 31.3% in the mountainous areas of the Americas and 13.8% in the mountainous areas of Africa from 1951-60 to 2012-21, and the likelihood of dengue transmission has increased by 12% during the same period.
- **Social Impact – Economic Losses:** Increased pressure on families and economies already strained by COVID-19 and international crises related to the cost of living and energy - threatening the socio-economic determinants on which good health depends. Heat exposure has led to potential loss of work hours and income losses estimated at extremely high values.
- **Impact on Food Security:** Shorter growing seasons for corn and wheat have led to an increase in malnutrition. Impact on Frontline Healthcare Already Weakened by COVID
- **Impact of the Urban Environment:** Increased green spaces, which cool urban areas, have been nullified by the spread of air conditioning (the number of households with air conditioning increased by 66% from 2000 to 2020).
- **Impact of Fossil Fuels:** Thirty years after the UN Framework Convention on Climate Change, carbon use in the global energy system has decreased by less than 1%, and global electricity production is still dominated by fossil fuels (82%), with renewable energy at 18%.

Glimmers of Hope

- The **individual commitment** to the health dimensions of climate change, essential to driving and enabling an accelerated response, increased from 2020 to 2021.
- Coverage of health and climate change in the media reached a new record in 2021, with a **27% increase** compared to 2020.
- **60%** of 194 countries focused their attention on the links between climate change and health during the **United Nations General Debate** in 2021.
- Local authorities are progressively identifying the **health risks** of climate change for the population.
- Although the healthcare sector is responsible for **5.2%** of global emissions (indicator 3.6), it has demonstrated significant leadership on climate, and **60 countries** have committed to transitioning to climate-resilient healthcare systems and/or low-carbon or carbon-zero healthcare systems as part of the COP26 health program, starting in July 2022.
- **Zero-carbon sources** accounted for **80%** of investments in electricity generation in 2021, and renewable energy reached **cost parity** with fossil fuels.

Determinants of Health

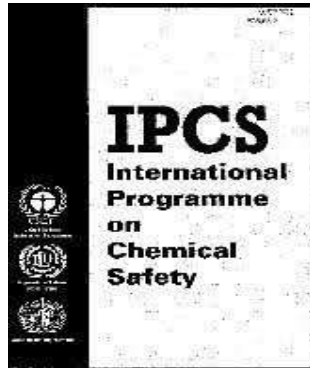
- Multiple “Determinants of Health
- Interconnection of Issues (Climate Change, Agricultural Policies, Pharmaceutical Patents, etc.)
- Competition Between Institutions in Health Matters



Food Security/Chemistry -> Health



- **1962-63 WHO/FAO Codex Alimentarius** is a set of guidelines and codes of good practices, standardized internationally, which contributes to the improvement of safety, quality, and fairness in global food trade.
- **1980 International Program on Chemical Safety (IPCS)** WHO/International Labour Organization/United Nations Environment Programme: establishes a scientific foundation for the safe use of chemicals and strengthens national capabilities and capacities for chemical safety.



Global Security -> Health-> Global Health Security

- Controversial Definition of "Security"(What is security? Security for whom? Security from what? How can security be achieved?)
- National security vs. human security: the point of contact -> spread of infectious diseases.

EXAMPLES:

2000: United Nations Security Council meeting on the impact of HIV/AIDS on peace and security in Africa (Note: the disease was spread by peacekeepers).

2014: <https://ghsagenda.org/>

CRITICISMS:

- Health shifts from being a "low politics" issue to a "high politics" issue.
- Equating health with security creates anxiety among vulnerable groups.
- Diverts attention from non-communicable diseases.



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Essential bibliography

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One Health Policy Legal Clinic: Protecting Health Beyond National and
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II part



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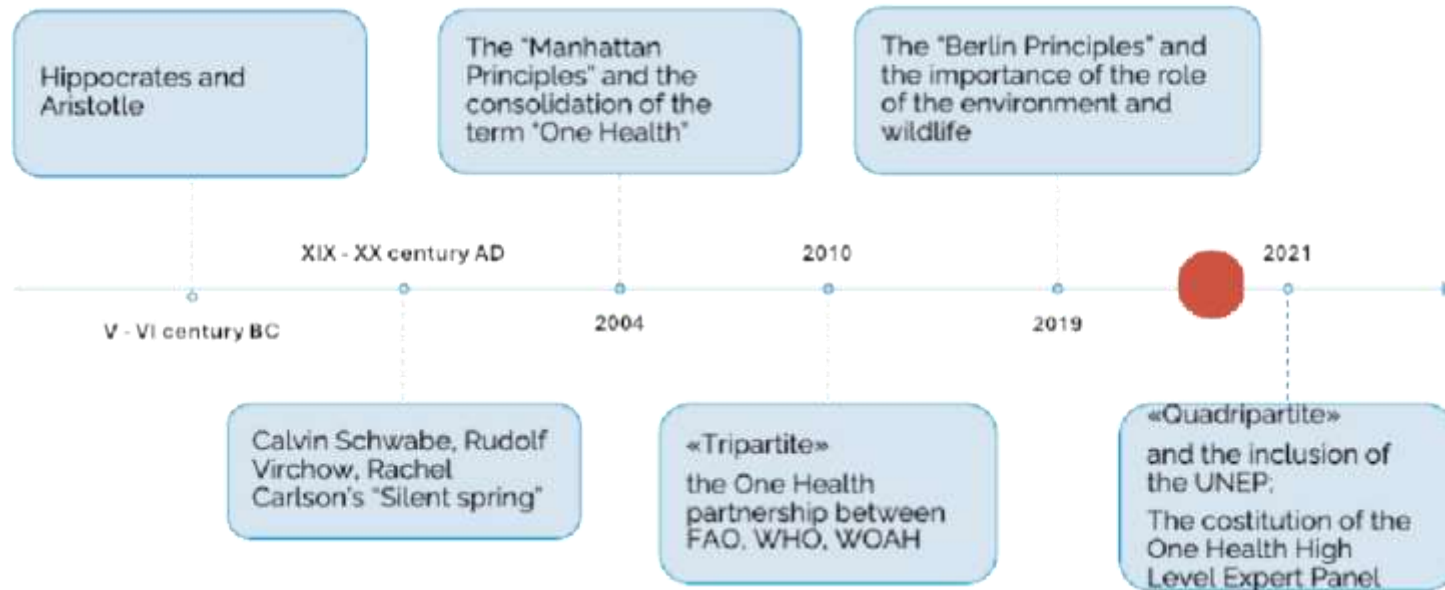


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One Health in Policy and Legislation: Moving Towards a Legal Principle?


Not a new concept




After Covid-19: what has changed?



One Health has broadened its scope to include the fight against climate change and biodiversity loss, the transition to sustainability, food and nutrition security, and social well-being



One Health is no longer the prerogative of human and veterinary medicine. Social sciences and law have clearly entered the debate



One Health is now part of the public discourse and the political and legal language



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Promoting coordination of One Health Through EU JARICA Tool

OH definition by OHHLEP (2022)

Parity between the three dimensions

Enlargement of the scope of application (no disease)

Appearance of the term “well being”

Link with sustainability challenges and SD

Focus on methodology

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** (OHHLEP).



The role of law in OH

- Law acts as “a fixture” between the OH interfaces as a crucial component of governance (Phelan 2017).
- Law and social science play a key role in translating OH into a functioning system made up by the interrelation of the three pillars of human health, animal health and environmental health (One Health European Joint Programme-OHEJP 2022 DOCUMENT ON THE INSTITUTIONALIZATION OF ONE HEALTH).
- Legislation is a powerful means to translate the OH objectives into concrete, sustainable and enforceable rights, obligations, and responsibilities, paving the way for inter-sectoral collaboration (FAO, 2020)
- The lack of robust regulatory frameworks and legal support is a barrier hindering the effective implementation of OH (see OH Joint Plan of Action by FAO, UNEP, WOA, WHO, 2022).

OH legislative definitions at global level

WHO Proposta di trattato internazionale sulle pandemie (versione 22 aprile 2024)

Le fasi del processo negoziale

Novembre 2020

Al Forum di Parigi per la pace il presidente del Consiglio europeo Charles Michel propone di elaborare uno strumento internazionale sulle pandemie.

Marzo 2022

Il Consiglio dell'Unione europea dà il via libera all'avvio dei negoziati.

Dicembre 2021

La sessione speciale dell'Assemblea mondiale della sanità concorda di dare il via alla redazione e alla negoziazione di una convenzione, un accordo o altro strumento internazionale sulla prevenzione, la preparazione e la risposta alle pandemie.

(È solo la seconda volta nella storia dell'OMS che il suo organo direttivo – l'Assemblea mondiale della sanità – si riunisce due volte nello stesso anno.)

Marzo 2023

I paesi dell'OMS avviano i negoziati su un primo progetto di accordo (il "progetto preliminare").



Maggio 2023

L'organo n+goziale presenta una relazione sullo stato di avanzate ntD dei lawori alla 76*Assemblea mondiale della



impegno politico e
inclusività globale

t

- più aqultè nell'aoccezo a
contromlsure medlche dl
qualità (vacEinl, Eeraple e
strumenti d'lagnostlEi)

Maggio 20M

Lo strum-9nto proposto è sortopouo all'esame della 77'
Assem blea mondiale della sanità.



principi, priorità e oblattld deriniti



eondMslonedl datl dl
monitoraggio, datl genetici,
campioni, tecnologie e
re4ativi benefkl



rafigoramento dota redlIenza
e delle capacità dl nsposLa
al le fMture pandemle sMI p lano
nazionale, regionale o globale



un approccio "Ona Health"
che colleghi la salute degli
esseri umanl, degli anlmail e
del piano\

Proposal for the WHO Pandemic Agreement

A77/10

Annex

Have agreed as follows:

Chapter I. Introduction

Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) “manufacturer” means public or private entities that develop and/or (DEL)/(RETAIN)] produce pandemic-related health products [[including] (DEL)] [for sale] (DEL)];

(b) “[One Health/one health] approach” means an integrated multisectoral approach that aims to sustainably balance and optimize the health of people, animals and ecosystems including by addressing various social, economic and environmental determinants of health in an equitable manner. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent.

[ALT(b) One health approach means multisectoral approach to pandemic prevention, preparedness and response that recognise the risk of pandemics links and interdependents with health of animals and environment and requires integrated disease surveillance, prevention and control at the animal-human interface.]

(c) [“PABS material and [PABS] information” [shall be defined in the instrument as referred to in Article 12]/ means the biological material from a pathogen with pandemic potential [shared through the PABS system], [as well as (DEL)/(RETAIN)] [[its] (DEL)] [or its sequence] [digital] [[sequencing/sequence] information [relevant to the development of pandemic-related health products] (DEL)]];]



World Health
Organization

RESUMED NINTH MEETING OF THE
INTERGOVERNMENTAL NEGOTIATING BODY TO
DRAFT AND NEGOTIATE A WHO CONVENTION,
AGREEMENT OR OTHER INTERNATIONAL
INSTRUMENT ON PANDEMIC PREVENTION,
PREPAREDNESS AND RESPONSE
Provisional agenda item 2

A/INB/9/3 Rev.1
22 April 2024

Proposal for the WHO Pandemic Agreement



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the European Union
Promoting operationalisation of One Health through EU digital tools

Article 3. Principles [and approaches] (DEL)]

To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the

Parties shall be guided, *inter alia*, by the following [principles (DEL)] [and approaches] (DEL):

1. The sovereign right of States, in accordance with the principles of international law, as enshrined in the Charter of the United Nations and the WHO Constitution, to legislate and to implement legislation, within their jurisdiction, [and their sovereign rights over their biological resources (DEL)/(RETAIN)];
 2. Full respect for the dignity, human rights and fundamental freedoms of all persons, and the enjoyment of the highest attainable standard of health of every human being [as well as the right to development] [as well as full respect for non-discrimination, gender equality and the protection of persons in vulnerable situations] (DEL)];
 3. Full respect [for the principles and applicable rules] of international humanitarian law for effective pandemic prevention, preparedness and response;
 4. Equity as a goal [, principle] and outcome of pandemic prevention, preparedness and response, striving for the absence of unfair, avoidable or remediable differences among and between individuals,
 5. Solidarity with all people and countries in the context of health emergencies, inclusivity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics, recognizing different levels of capacities and capabilities [, as well as the special circumstances of small island developing States]; and
- [5bis. Full recognition of the special circumstances of [developing countries, in particular] (DEL)] small island developing States and of least developed countries in relation to pandemic prevention, preparedness and response;]
6. The best available science and evidence as the basis for public health decisions for pandemic

Art. 5 One Health (I)

Article 5. One Health approach for Pandemic Prevention, Preparedness and Response

1. The Parties shall promote a One Health approach for pandemic prevention, preparedness and response [, on a voluntary basis (DEL)], recognizing the interconnection between the health of people, animals and the environment, that is coherent, integrated, coordinated and collaborative among all relevant organizations, sectors and actors, as appropriate, in accordance with national and/or domestic law, and applicable international law, and taking into account national circumstances.

2. The Parties shall take measures, as appropriate aimed at identifying and addressing, in accordance with national and/or domestic law, and applicable international law, the drivers of pandemics and the emergence and re-emergence of infectious disease at the human-animal-environment interface, through the introduction and integration of interventions into relevant pandemic prevention, preparedness and response plans subject to the availability of resources.

Art. 5 One Health (II)

A77/10

Annex

3. Each Party shall, in accordance with national or domestic law and taking into account national and regional contexts, and subject to the availability of resources, take [measures, as appropriate,] [appropriate measures] aimed at promoting human, animal and environmental health, with support, as necessary and upon request, from WHO and other relevant intergovernmental organizations, including by:

(a) Developing, implementing and reviewing relevant national policies and strategies that reflect a One Health approach as it relates to pandemic prevention, preparedness and response;

(b) [[Promot[ing] the effective and meaningful engagement of communities in the development and implementation of policies, strategies and measures [related to One Health;] [to prevent, detect and respond to outbreaks (DEL)]; (DEL)] *Comment Refer to text in Art 17* and

(c) Promoting or establishing joint training and continuing education programmes for the workforce at the human, animal and environmental interface to build relevant and complementary skills, capacities and capabilities, in accordance with a One Health approach.

(NOTE: Competent intergovernmental organizations to be identified in the WHA resolution)

4. [[[The Parties shall further define] The modalities, terms and conditions and operational dimensions of a One Health approach [[, including prevention,] (DEL)] [within guidelines to be agreed by the COP] [for pandemic prevention, preparedness and response supportive of and consistent with [articles 4 and 5,](DEL)/this article][, shall be further defined in a[n] [legally binding] instrument [operational no later than 31 May 2026 and] that takes into consideration the provisions of the International Health Regulations (2005) [the first of which shall be operational by 31 May 2026] [and will be [operational] [to be agreed] by 31 May 2026]]. (DEL)] (DEL)]

OH in EU juridical tools

EU REGULATORY FRAMEWORK
OH mentioned more than 300 times in EU documents
Gradually increase (10 times in 2017, 27 in 2018), but peaking from 2020 (44 in 2020, 78 in 2021, 79 in 2022, 66 in 2023...)
One Health is mentioned in 10 regulations, 6 decisions, 27 communications
From a policy tool to a legal tool (1 Reg. in 2016; 0 in 2017; 1 in 2018; 0 in 2019; 0 in 2020; 4 in 2021; 4 in 2022)

F. Coli, H. Schebesta, 2023

REG (EU) 2021/522 EU4Health Programme

REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 March 2021

establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014

11 Due to the serious nature of **cross-border threats to health**, the Programme should **support coordinated public health measures** at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage any future health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council [\(9\)](#) and other relevant mechanisms and structures referred to in the communication of the Commission of 11 November 2020 entitled 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', including actions directed at strengthening preparedness planning and response capacity at national and Union level, at reinforcing the role of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and at establishing a health emergency preparedness and response authority. Such actions could include building capacity for responding to health crises, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, provision of health information, and platforms to share best practices. In this context, the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness and surveillance, and the management capacity and response capacity of actors at Union and Member State levels, including contingency planning and preparedness exercises, **in keeping with the 'One Health' and 'Health in All Policies' approaches**. The Programme should facilitate the setting up of an integrated cross-cutting risk communication framework for all phases of a health crisis, namely prevention, preparedness and response.

cross-
border
health
threats

31 As the optimal delivery and use of medicinal products, and of antimicrobials in particular, yield benefits for individuals and health systems, the Programme should promote their prudent and efficient use in accordance with the One Health approach, with the 'European One Health Action Plan against Antimicrobial Resistance (AMR)' set out in the communication of the Commission of 29 June 2017, and with the 'European Union Strategic Approach to Pharmaceuticals in the Environment' set out in the communication of the Commission of 11 March 2019. The Programme should also foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products.

Fight against
AMR

Definitions

- (5) 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;

OH implementation in EU

EU ONE HEALTH METHODS OF IMPLEMENTATION

Guiding principle REG 2021/522 (EU4Health) OH as a binding legal guiding principle in the pursuit of general and specific objectives related to health
COM/2022/404 (Conference on the future of Europe)
"One Health Approach", which should be emphasized as a horizontal and fundamental principle encompassing all EU policies"

Tool for policy-making Decision 2022/591 (8th Environment Action Programme)

"Importance of applying the multi-sectoral One Health approach in policy-making"

Organisational method Nov 2023-May 2024
Cross-EU agency task force
European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Environment Agency (EEA), European Food Safety Authority (EFSA) and European Medicines Agency (EMA)

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Essential bibliography



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Promoting operationalisation of One Health through EU Juridical Tools



Financed by
the European Union