

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

3 Aprile 2025

1st part: One Health and the EU legal framework

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

prof. Flaminia Aperio Bella (PROHTECT coordinator)



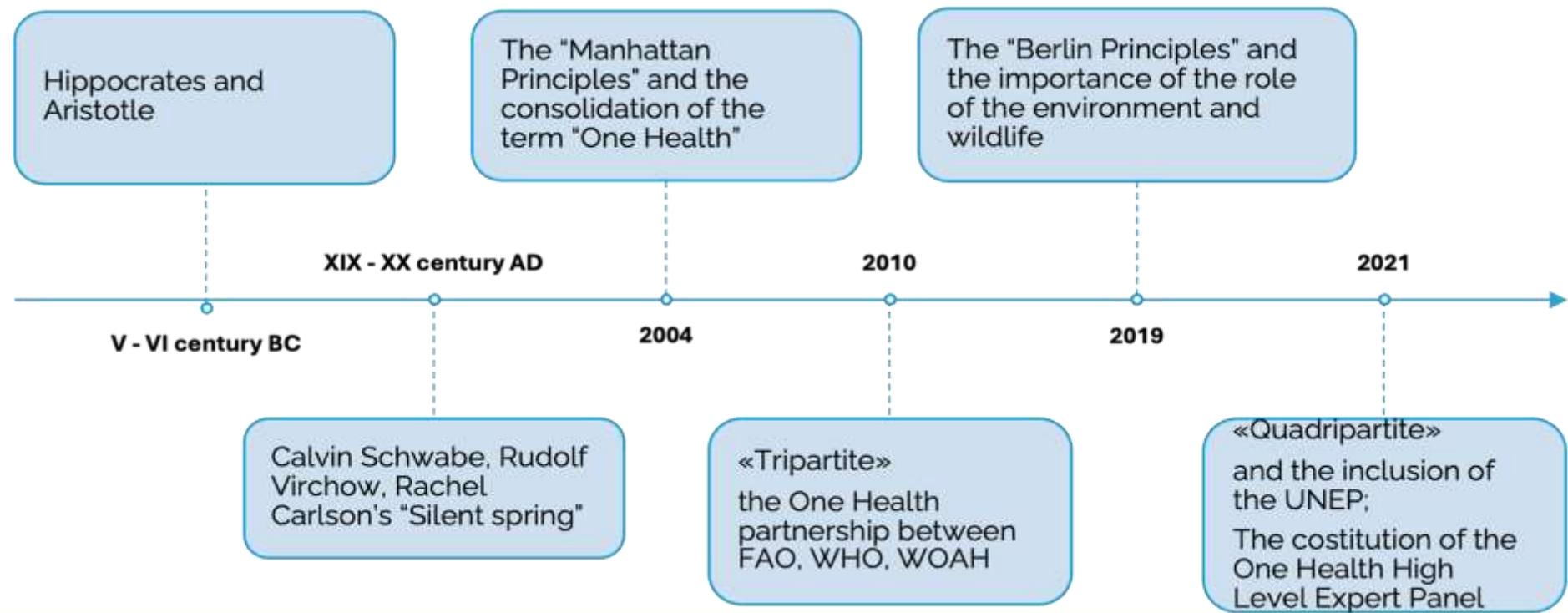
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Promoting operationalisation of One Health Through EU Juridical Tool

# Not a new concept



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Preventing operationalisation of One Health Through EU Jurisical Trail



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# 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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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 eco-systems) are closely linked and interdependent.

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 healthy food, water, energy, and air, taking action on climate change and contributing to sustainable development.



# 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).



BRILL

Publications

Subjects

## One Health and Pathogen Sharing: Filling the Gap in the International Health Regulations to Strengthen Global Pandemic Preparedness and Response

In: *International Organizations Law Review*

Authors: Stefania Negri and Mark Eccleston-Turner

Online Publication Date: 29 Jun 2022

## SWP Comment

NO. 43 JULY 2023

### “One Health” and Global Health Governance

Design and implementation at the international, European, and German levels

Michael Bayerlein and Pedro A. Villarreal

CeSDirSan

REPORT NO. CSDirSan

#### ONE HEALTH: LA TUTELA DELLA SALUTE OLTRE I CONFINI NAZIONALI E DISCIPLINARI

PER UN APPROCCIO OLISTICO  
ALLA SALUTE UMANA,  
ANIMALE E AMBIENTALE

COORDINATA DA  
FRANCESCA APOSTOLI BOLA

COORDINATA DA  
ALESSANDRA CIOCCANTE

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20110765 - Attività: One Health”, la tutela della salute oltre i confini nazionali e disciplinari



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# 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<br>(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

# OH in EU Pharma Strategy (1)

## 6 Main Areas of EU Pharmaceutical Strategy

- 1) Better access to innovative and affordable medicines for patients and national health systems
- 2) Promoting innovation and competitiveness through an efficient and simplified regulatory framework
- 3) Effective incentives for innovation
- 4) Addressing shortages of medicines and ensuring security of supply.
- 5) Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach.
- 6) Make medicines more environmentally sustainable.



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# OH in EU Pharma Strategy (2)

## CONTEXT OF THE PROPOSAL

### Reasons for and objectives of the proposal

- **Consistency with other Union policies**

The EU pharmaceutical legislation described above has close links with several other related pieces of EU legislation. The 'Clinical Trials Regulation' (Regulation (EU) No 536/2014) <sup>10</sup> allows for more efficient approval of clinical trials in the EU. Regulation (EU) 2022/123 <sup>12</sup> strengthens the role of the European Medicines Agency in order to facilitate a coordinated EU-level response to health crises. The EMA fees legislation <sup>11</sup> contributes to providing adequate financing for the EMA's activities, including respective remuneration to national competent authorities for their contribution to completing the EMA's tasks.

There are also links with EU regulatory frameworks for other health products. EU legislation on blood, tissues and cells (BTC) <sup>14</sup> is relevant, as some substances of human origin are starting materials for medicinal products. The EU regulatory framework for medical devices <sup>15</sup> is also relevant, as there are products that combine medicinal products and medical devices.

Furthermore, the objectives of the proposed reform of the pharmaceutical legislation are consistent with those of a number of broader EU policy agendas and initiatives.

In terms of promoting innovation, Horizon Europe <sup>16</sup>, a key funding programme for EU research and innovation, and Beating Cancer Plan <sup>17</sup> both support research and development of new medicinal products. In addition, innovation in the pharmaceutical sector is promoted by the intellectual property frameworks, on patents under the national patent laws, the European Patent Convention and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and on supplementary protection certificates under the EU SPC Regulation <sup>18</sup>. The intellectual property action plan <sup>19</sup> under the Industrial Strategy includes modernising the system of supplementary protection certificates (SPCs). SPCs extend certain patent rights to protect innovation and compensate for lengthy clinical trials and marketing authorisation procedures. With regard to addressing unmet medical needs in the area of antimicrobial resistance, the proposed reform of the pharmaceutical legislation will contribute to the objectives of the European one health action plan against antimicrobial resistance (AMR) <sup>20</sup>.



## Tackling Antimicrobial Resistance in a One Health approach

JUNE 2023

### 1 THE AMR CHALLENGE



- ▶ Antimicrobial resistance (AMR) occurs **when microbes change over time and stop responding to medicines** designed to kill them.
  - ▶ infections harder to treat
  - ▶ higher risk of diseases, severe illnesses, and death.
- ▶ AMR **affects humans, animals, and plants**, as well as the environment, impacting healthcare and food production.
- ▶ It is a **cross-border issue** and is one of the **top 3 health threats** faced by the EU.

AMR CAUSES 35 000 DEATHS EVERY YEAR IN THE EUROPEAN UNION AND LEADS TO HIGH COSTS, INCLUDING €1.58N ANNUALLY FOR OUR HEALTHCARE SYSTEMS.

# AMR: a “silent pandemic”



## Antimicrobial resistance in the EU/EEA (EARS-Net) - Annual Epidemiological Report 2023

Scientific and technical publications

In Europe, more than 670,000 infections with antibiotic-resistant germs occur every year, which cause more than 35,000 deaths, **almost a third of which occur in Italy, making it the leading country at the European level.**

Antibiotico-resistenza

Consumi di antibiotici in aumento del 6,3%. Tutti i numeri della pandemia silente dell'antibiotico resistenza che in Italia rischia di diventare la prima causa di morte nel 2050

We get sicker and spend more and more, because super bacteria are responsible for a significant absorption of resources (health and non-health) that amount to about 1.5 billion euros per year

## World Leaders Approve Milestone Commitment to Reduce Deaths from Antibiotic Resistance by 10% by 2030

Antimicrobial Resistance 26/09/2024 · Elaine Ruth Fletcher

Share this:



UN High Level Meeting, presided over by heads of FAO and UNEP (far left), and WHO WOH (right), approves new declaration to fight AMR.

In the absence of stronger, swifter public health action, it is unlikely that the EU will reach all its AMR targets by 2030.

# AMR and OH

*"The threat of AMR cuts across the health of humans, animals, agriculture and our environment, and so must its solutions,"*

(WHO Director General Dr Tedros Adhanom Ghebreyesus at the UN High Level Meeting on AMR, september 2024)

- The inappropriate use of antimicrobials, both in **humans and in animals**, is a main driver behind increased levels of emergence and spread of multi-resistant bacteria.
- The **environment** is increasingly acknowledged as a contributor to the development and spread of AMR in humans and animals
- **Residues of medicinal products** are widely found in groundwaters and surface waters, including coastal waters and soils, and several publications show that **antibiotic residues can contribute to AMR.**

Drug-resistant microorganisms can be found in humans, animals, plants, food, wastewater and in the environment -> An **integrated surveillance** of findings is necessary in order to rapidly detect and prevent outbreaks and to tackle AMR across sectors.

# OH and environmentally sustainable medicine

The production, use and improper disposal of pharmaceuticals may have negative impacts on the environment.

Action is required **throughout the lifecycle of medicines (it is not only a question of waste)**

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## MORE ENVIROMENTALLY SUSTAINABLE MEDICINES



Production of medicines in a way that is better for the environment, biodiversity and human health:

- ▶ **Strengthened environmental risk assessments for all medicines**, including those already authorized, to limit the potential adverse effects of medicines on the environment and public health.
- ▶ **Fewer pharmaceutical substances** including antimicrobials **in the environment** due to more environmentally friendly production, use or proper disposal of medicines.

### Flagship initiatives on quality and environmental sustainability

- ▶ Propose to revise the manufacturing and supply provisions in the pharmaceutical legislation to improve the transparency and reinforce oversight of the supply chain and clarify responsibilities to ensure overall environmental sustainability, safeguard the quality of medicines and ensure preparedness for new manufacturing technologies – 2022.
- ▶ Propose to revise the pharmaceutical legislation to strengthen the environmental risk assessment requirements and conditions of use for medicines, and take stock of the results of research under the innovative medicines initiative – 2022.



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# Comparing EU Pharma Strategy and in EU4HEALTH Regulation (1)

| EU Pharma Strategy                                                                                                           | Reg. 2021/522 EU4HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach; | <p>(31) As the <b>optimal delivery and use of medicinal products</b>, and of antimicrobials in particular, yield benefits for individuals and health systems, the Programme should promote their <u>prudent and efficient use in accordance with the One Health approach</u>, 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 (...)</p> <p>Article 4 - Specific objectives</p> <p>The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities <b><u>in keeping with the One Health approach, where applicable:</u></b> (...)</p> <p>(c) (...) <b>supporting the prudent and efficient use of medicinal products, in particular antimicrobials</b> (...)</p> |
| Make medicines more environmentally sustainable.                                                                             | <p>(31) (...) The Programme should also foster measures to strengthen the assessment and appropriate management of <b><u>environmental risks associated with the production, use and disposal of medicinal products</u></b>.</p> <p>Article 4 - Specific objectives</p> <p>The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities <b><u>in keeping with the One Health approach, where applicable:</u></b> (...)</p> <p>(c) (...) <b>supporting (...) the development of medicinal products that are less harmful for the environment, as well as the environmentally friendly production and disposal of medicinal products and medical devices;</b></p>                                                                                                                                                                                                                                                       |

# Comparing EU Pharma Strategy and in EU4HEALTH Regulation (2)

| EU Pharma Strategy | Reg. 2021/522 EU4HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ✗                  | <p>Article 2 – Definitions (...)</p> <p>(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;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| ✗                  | <p>Article 3 - General objectives</p> <p>The Programme shall have a Union added value and complement the policies of the Member States, in order to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities. It shall pursue the following general objectives <b>in keeping with the One Health approach, where applicable:</b> (...)</p> <p><b>(c) improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products</b></p> <p>Article 4 - Specific objectives</p> <p>The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities <b>in keeping with the One Health approach, where applicable:</b> (...)</p> <p><b>(c) supporting actions to enhance the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union(...)</b></p> |

Definition of OH

link between OH and availability, accessibility and affordability of medical products, MD and crisis-relevant products

# Comparing EU Pharma Strategy and in EU4HEALTH Regulation (3)

## EU Pharma Strategy

## Reg. 2021/522 EU4HEALTH



(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 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**...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. (...)

Organisational dimension of OH



# Cross-agency OH task force



**2023:** establishment of Cross- agency One Health task force including EU agencies that have a technical and scientific mandate on topics falling under the OH umbrella

**2024:** Publication of a «framework for action» containing a set of strategic objectives that the five agencies intend to pursue together to promote OH implementation.

The ultimate goal is to strengthen the ability of the EU and its Member States to **respond to health crisis** through a **more permanent and established form of transdisciplinary cooperation**

The task force will not act as a decision-making body (but may propose recommendations for action) and will have an **advisory role**

European Parliament resolution on the COVID-19 pandemic: [lessons learned and recommendations for the future \(2022/2076\(INI\)\)](#) item 251: *Calls for the establishment of a European cross-agency task force dedicated to the One Health approach to **advance transdisciplinary research and cross-sectoral scientific advice.***

Figure 1: Strategic objectives of the cross-agency One Health task force framework for action



# 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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# Further implementation of the OH approach in the Future of Pharmaceutical Regulation?

## Challenges:

- sustainable development has three dimensions: economical, ecological and **social**.
- equity lies at the hart of OH
- “vaccine equity” , recognize world access to vaccines as a global public good, and ensure their universal availability, together with medicines and medical equipment (CIDCE draft convention on Pandemics based on OH approach)

**C** ENTRE  
**I** NTERNATIONAL de  
**D** ROIT  
**C** OMPARÉ de l'  
**E** NVIRONNEMENT

<https://cidce.org/en/pandemics-and-environment-2/>

### Draft Convention on Pandemics

At the initiative of the International Center for Comparative Environmental Law (CIDCE), the draft convention on pandemics was drawn up by a group of lawyers coordinated by Michel Prieur, President of CIDCE.

After preparatory work by the CIDCE in June / July 2021, the group of lawyers was formed at the end of August. By videoconference, it held 12 plenary meetings, from September 13 to November 28, as well as several thematic breakout meetings during the same period.

Along with the development and discussion of the draft convention, a rationale for its adoption was prepared in two forms: an executive summary and an explanatory version.

CIDCE led this work in partnership with the Normandy Chair for Peace, which facilitated the holding of plenary meetings, and the Global Pandemic Network (GPN), which spearheaded the development of the rationale.

According to the [latest draft](#) of the pandemic agreement, the most controversial part of the agreement concerns the **developing a pathogen access and benefit-sharing (PABS) system** **It will now be addressed via a separate “instrument”** and no deadline for its finalisation has been set.

Some representative of developing countries engaged in the negotiations appealed for **equity to remain the focus of the talks** to “address inequities that were experienced by most developing countries during the COVID-19 pandemic”.

Onscreen text reflecting progress up to Thursday 19 September at  
17:30 CEST



World Health  
Organization

SEVENTY-SEVENTH WORLD HEALTH ASSEMBLY  
Provisional agenda item 13.4

A77/10  
27 May 2024

**Intergovernmental Negotiating Body to draft and  
negotiate a WHO convention, agreement or other  
international instrument on pandemic prevention,  
preparedness and response**

**Report by the Director-General**

1. The Director-General has the honour to transmit to the Seventy-seventh World Health Assembly the outcome of the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (see Annex), in line with decision SSA2(5) (2021).

# Pathways to move forward

- 1) OH goes beyond diseases and cures and has the potential to encompass all non-medical factors that influence health outcomes

A broader understanding of Health - Adopt a holistic approach to health, addressing, beyond diseases and cures, health literacy and prevention, and fostering a shared understanding of the challenges faced by those who are ill or disabled, in line with the “One Health Approach”, which should be emphasized as a horizontal and fundamental principle encompassing all EU policies (COM/2022/404 final)



Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (WHO 1946)

The fundamental conditions and resources for health are peace, shelter, education, food, income, a stable ecosystem, sustainable resources, social justice and equity (Ottawa Charter for Health Promotion 1986)

## 2) We need a shared language

The comprehensive definition of OH allows us to better evaluate relations with other holistic and interdisciplinary approaches that exist to safeguard health



### 3) OH is not only about the external dimension of Health

**(1) Deliver better health and well-being of people across the life course;**

**(2) Strengthen health systems and advance universal health coverage; and a**

**(3) Prevent and Combat health threats, including pandemics, applying a One Health approach.**



EU Global Health Strategy, 2022

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# Essential bibliography

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

3 Aprile 2025

2nd part: One Health and the Italian legal framework

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

prof. Flaminia Aperio Bella (PROHTECT coordinator)



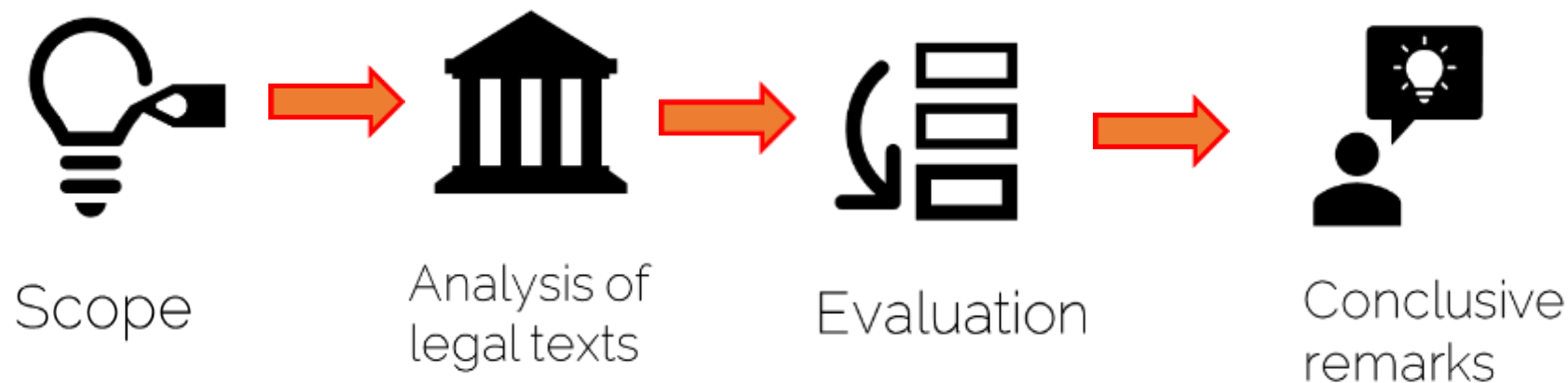
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# Outline



# Focus on Italian policies and legislation

What remains out of my focus: broader reflection on the growing interest on One Health in Italy

- from the viewpoint of the public

....from the viewpoint of initiatives of italian institutions



## ADESIONI E OBIETTIVI

### One Health: presentato alla Camera l'intergruppo parlamentare

22 Giugno 2023



Sono 26, tra deputati e senatori, i parlamentari di ogni schieramento che hanno presentato oggi alla Camera l'intergruppo "One Health". ANMVI e FNOVI nel Comitato Tecnico-Scientifico.

*"Un plauso a questa iniziativa che saprà dare il giusto peso alla componente veterinaria nelle politiche One Health",* il Presidente dell'ANMVI, **Marco Melosi**, commenta la nascita dell'intergruppo parlamentare "One Health", presentato oggi pomeriggio alla Camera dei Deputati, su proposta degli onorevoli **Luciano Ciocchetti** (Fdi) e **Ylenia Lucaselli** (Fdi) al quale hanno aderito, ad oggi, 26 tra deputati e senatori di tutti gli schieramenti.

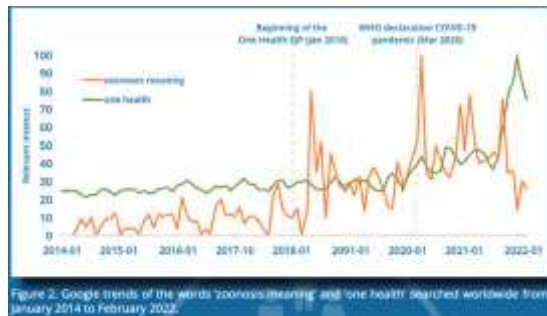


Figure 2: Google trends of the words 'zoonosis/meat' and 'one health' searched worldwide from January 2014 to February 2022.



### Italian National Institute of Health report on OH initiatives (2018-2021)

<https://www.iss.it/documents/20126/0/All+for+OH+-+ISS+Final+Draft+18-5.pdf/29789139-0a66-ff8e-c4e6-228f4188bfa9>

...from the viewpoint of academia (research and formative initiatives)

S. Hurrebold-Dachmann, et al.

One Health 10 (2020) 100146

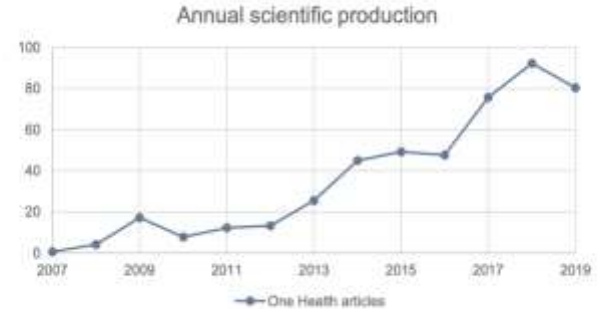


Fig. 2. Ratio of annual scientific production of One Health articles.



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Promoting operationalisation of One Health Through EU JARCET Tool

# Analysis of a selection of legal texts



A) Policy documents

**B) Legislation (primary legislation and subordinate legislation – regulations-)**

C) Italian constitution

- express reference to One Health
- selection



# 1) National Prevention Plan 2020-2025'. Ministry of Health on 6th August 2020

## One Health centrality from a quantitative and qualitative viewpoint

- mentioned 50 times in 200 pages.
- described as the first "vision" and "principle" that the plan aims to "reinforce"
- connected with Agenda 2030 SDGs ("holistically address all socio-cultural, environmental, relational and emotional determinants that influence health")
- methodologically applied by the Plan ("collaboration at all levels" "multistakeholder governance; shared and participatory programming; active involvement of communities in decision-making processes")

Which role for Planetary Health?

- defined
- mentioned 5 times,
- presented contradictory manner in its relation with OH



## Piano Nazionale della Prevenzione 2020-2025



the achievement of the highest attainable standard of health, wellbeing, and equity worldwide through judicious attention to the human systems—political, economic, and social—that shape the future of humanity and the Earth's natural systems that define the safe environmental limits within which humanity can flourish" (2015, [Lancet Commission on planetary health](#))

## 2.1 L'ottica *One Health* e gli obiettivi di sviluppo sostenibile dell'Agenda 2030 dell'ONU

Il PNP 2020-2025 rafforza una visione che considera la salute come risultato di uno sviluppo armonico e sostenibile dell'essere umano, della natura e dell'ambiente (*One Health*).

Per garantire a tutti i cittadini un futuro all'insegna di uno sviluppo in salute e più sostenibile, occorre affrontare tutti i determinanti socio-culturali, ambientali, relazionali ed emotivi che influenzano la salute, attraverso una programmazione *multistakeholder*, condivisa e partecipata, con il coinvolgimento attivo delle comunità nei processi decisionali. Ciò è in linea con l'approccio *One Health* che, riconoscendo che la salute delle persone, degli animali e degli ecosistemi sono interconnesse, promuove l'applicazione di un approccio multidisciplinare, intersettoriale e coordinato per affrontare i rischi potenziali o già esistenti che hanno origine dall'interfaccia tra ambiente-animali-ecosistemi.

L'approccio *One Health* consente di affrontare la questione trasversale della biodiversità e della salute umana, così come il contrasto efficace all'antimicrobico-resistenza, problema crescente di dimensioni globali, o come il contrasto all'emergenza di epidemie e pandemie che trovano origine nelle manomissioni e degrado degli ecosistemi con conseguenti trasferimenti di patogeni (*spillover*) dalla fauna selvatica a quella domestica, con successiva trasmissione all'uomo.

La drammatica recente esperienza della pandemia da SARS-COV 2 ha rimarcato come uomo, animali e ambiente siano fortemente connessi in una relazione di interdipendenza e ha reso consapevoli che potrebbero presentarsi nuove emergenze per la diffusione di altri microorganismi patogeni a causa di modifiche e trasformazioni globali degli ecosistemi, anche conseguenti ad attività umane irrispettose dell'ambiente (deforestazione, allevamenti intensivi, ecc.). L'epidemia ha aumentato la consapevolezza che le risorse del pianeta, sia naturali sia di beni materiali, non sono illimitate e che è necessario abituarsi a ragionare in termini di risparmio e di uno stile di vita diverso, più misurato e solidale. Inoltre ha portato alla luce le già note implicazioni dell'equità sulla salute, dal momento che le fasce deboli della popolazione (anziani, malati cronici, ecc.), le quali non sono equamente distribuite rispetto a fattori sociali, geografici, ecc., sono risultate essere quelle maggiormente colpite dal virus più e suscettibili alle sue conseguenze sfavorevoli.

L'approccio *One Health* mira a ricomprendere in una strategia comune sanità umana e animale, contrasto del cambiamento climatico e difesa della biodiversità del pianeta, secondo una logica in cui la prevenzione rappresenta l'elemento centrale per salvaguardare in ogni comunità, dal livello locale fino al livello mondiale, "beni comuni" come la salute, l'ambiente e la biodiversità.

L'approvazione dell'Agenda 2030, con i suoi 17 obiettivi, concepiti come inscindibili e pensati in modo da integrarsi e interagire tra loro, ha rappresentato una evoluzione verso un approccio combinato, in cui tutti gli obiettivi tengono conto degli aspetti economici, sociali e ambientali e mirano a porre fine alla



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## 2) “Italian Action Plan vs Antimicrobial Resistance (AMR) 2022-2025” Ministry of Health on 30th November 2022

### One Health approach in its traditional context but with new features

- applied in a traditional field (fight against AMR)
- mentioned as first general objective («Strengthen the One Health approach, including through the development of coordinated national surveillance»);
- methodologically applied by the Plan (inclusive and integrated governance)
- defined («is an approach for designing and implementing programmes, policies, regulations and research that involves different sectors communicating and working together to improve public health outcomes. It is particularly important in combating antibiotic resistance, **but also for other areas such as** zoonoses control and food safety»)



Which role for Planetary Health?  
None

## “Piano Nazionale di Contrasto all’Antibiotico-Resistenza (PNCAR) 2022-2025” MS approvato in Conferenza Stato-Regioni il 30 novembre 2022

«nasce con l’obiettivo di fornire al Paese le linee strategiche e le indicazioni operative per affrontare l’emergenza dell’ABR nei prossimi anni, seguendo un approccio multidisciplinare e una visione One Health, promuovendo un costante confronto in ambito internazionale e facendo al contempo tesoro dei successi e delle criticità del precedente piano nazionale.

La Strategia nazionale di contrasto all’ABR definisce inoltre sei obiettivi generali per ridurre

- 1 Rafforzare l’approccio One Health, anche attraverso lo sviluppo di una sorveglianza nazionale coordinata dell’ABR e dell’uso di antibiotici, e prevenire la diffusione della ABR nell’ambiente;
- 2 Rafforzare la prevenzione e la sorveglianza delle ICA in ambito ospedaliero e comunitario;
- 3 Promuovere l’uso appropriato degli antibiotici e ridurre la frequenza delle infezioni causate da microrganismi resistenti in ambito umano e animale;

*One Health*: è un approccio per disegnare e implementare programmi, politiche, normative e ricerca che prevede che diversi settori comunichino e lavorino insieme per **migliorare gli esiti di salute pubblica**. È particolarmente importante nel contrasto all’antibiotico-resistenza, ma anche per altre aree quali controllo delle zoonosi e sicurezza alimentare.



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# 3) Decree 23 May 2022, No. 77 Regulation defining models and standards for the development of primary care in National health service

## One Health enters in hard law as a strategy with broader scope

- described as a «strategy» to be considered in the promotion, prevention and protection of community health
- presented in “weak” relation with Agenda 2030 SDGs (“health as a result of harmonious and sustainable development of human beings, nature and the environment”)
- only mentioned with reference to the method (“fostering a close synergy with the different articulations of local communities, agencies and institutions concerned”)

Which role for Planetary Health?

contradictory definitions

-synonym for taking care of the person in holistic terms, with a focus on mental health and the most fragile conditions

- holistic approach that complement OH

## COVID-19 crisis- Next generation EU – Recovery and Resilience Facility



## National Recovery Plan

### MISSIONE 6: SALUTE



# 4) Decree-Law 30 April 2022, No. 36 Further urgent measures to implement the National Recovery and Resilience Plan

Establishing the **National System for Preventing Health from Environmental and Climate Risks** ("SNPS" art. 27)

## One Health as a method

SNPS shall act "through the application of the integrated 'one-health' approach, interacting with the National Network System for the environmental protection

OH is

- connected with a broader dimension involving social dimension and equity values
- not fully methodologically applied (reference to communities and vulnerable people but no means for their involvement)
- not reflected in the composition of the SNPS (governance linked to the health sector)
- not neglected in its environmental dimension as far as SNPS is conceived to interact with the National Network System for the environmental protection SNPA)



Which role for Planetary Health?  
As an evolution of One Health

d.l. 30 aprile 2022, n. 36 Ulteriori misure urgenti per l'attuazione del Piano nazionale di ripresa e resilienza (PNRR), conv.

con mod. dalla L. 29 giugno 2022, n. 79 (in G.U. 29/06/2022, n. 150)

## **Art. 27**

### **Istituzione del Sistema nazionale prevenzione salute dai rischi ambientali e climatici**

1. Allo scopo di migliorare e armonizzare le politiche e le strategie messe in atto dal Servizio sanitario nazionale per la prevenzione, il controllo e la cura delle malattie acute e croniche, trasmissibili e non trasmissibili, associate a rischi ambientali e climatici, *e delle zoonosi* è istituito il Sistema nazionale prevenzione salute dai rischi ambientali e climatici, di seguito «SNPS».

2. Il SNPS, mediante l'applicazione dell'approccio integrato «one-health» nella sua evoluzione «planetary health» e tramite l'adeguata interazione con il Sistema nazionale a rete per la *protezione dell'ambiente*, di cui alla [legge 28 giugno 2016, n. 132](#), di seguito «SNPA», concorre al perseguimento degli obiettivi di prevenzione primaria correlati in particolare alla promozione della salute, alla prevenzione e al controllo dei rischi sanitari associati direttamente e indirettamente a determinanti ambientali e climatici, anche derivanti da cambiamenti socio-economici, valorizzando le esigenze di tutela delle comunità e delle persone vulnerabili o in situazioni di vulnerabilità, in coerenza con i principi di equità e prossimità.

## Segue: le funzioni del SNPS

3. Ai fini di cui al comma 2, il SNPS svolge le seguenti funzioni:

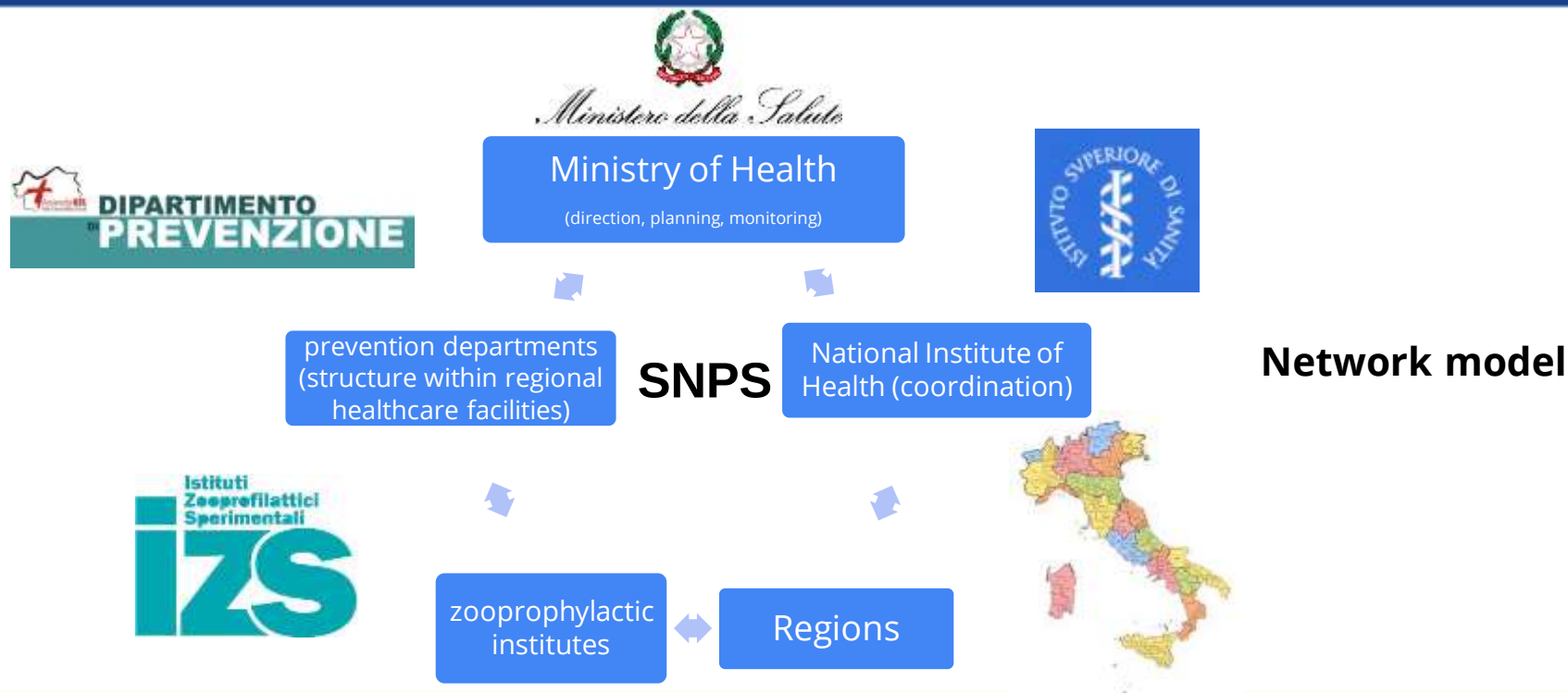
- a) identifica e valuta le problematiche sanitarie associate a rischi ambientali e climatici, per contribuire alla definizione e all'implementazione di politiche di prevenzione attraverso l'integrazione con altri settori;
  - b) favorisce l'inclusione della salute nei processi decisionali che coinvolgono altri settori, anche attraverso attività di comunicazione istituzionale e formazione;
  - c) concorre, per i profili di competenza, alla definizione e all'implementazione degli atti di programmazione in materia di prevenzione e dei livelli essenziali di assistenza associati a priorità di prevenzione primaria, assicurando la coerenza con le azioni in materia di livelli essenziali delle prestazioni tecniche ambientali (LEPTA), di cui all'articolo 9 della legge 28 giugno 2016, n. 132;
  - d) concorre alla individuazione e allo sviluppo di criteri, metodi e sistemi di monitoraggio integrati, anche avvalendosi di sistemi informativi funzionali all'acquisizione, all'analisi, all'integrazione e all'interpretazione di modelli e dati;
  - e) assicura il supporto alle autorità competenti nel settore ambientale per l'implementazione della valutazione di impatto sanitario (VIS) nell'ambito della valutazione ambientale strategica (VAS), della valutazione di impatto ambientale (VIA) e dell'autorizzazione integrata ambientale (AIA);
- ((e-bis) predispone una relazione annuale in merito ai campi di intervento, alle prospettive di ricerca e di implementazione delle proprie funzioni e ai possibili interventi normativi, ai fini della sua trasmissione alle Camere da parte del Governo)

## Segue: la composizione del SNPS

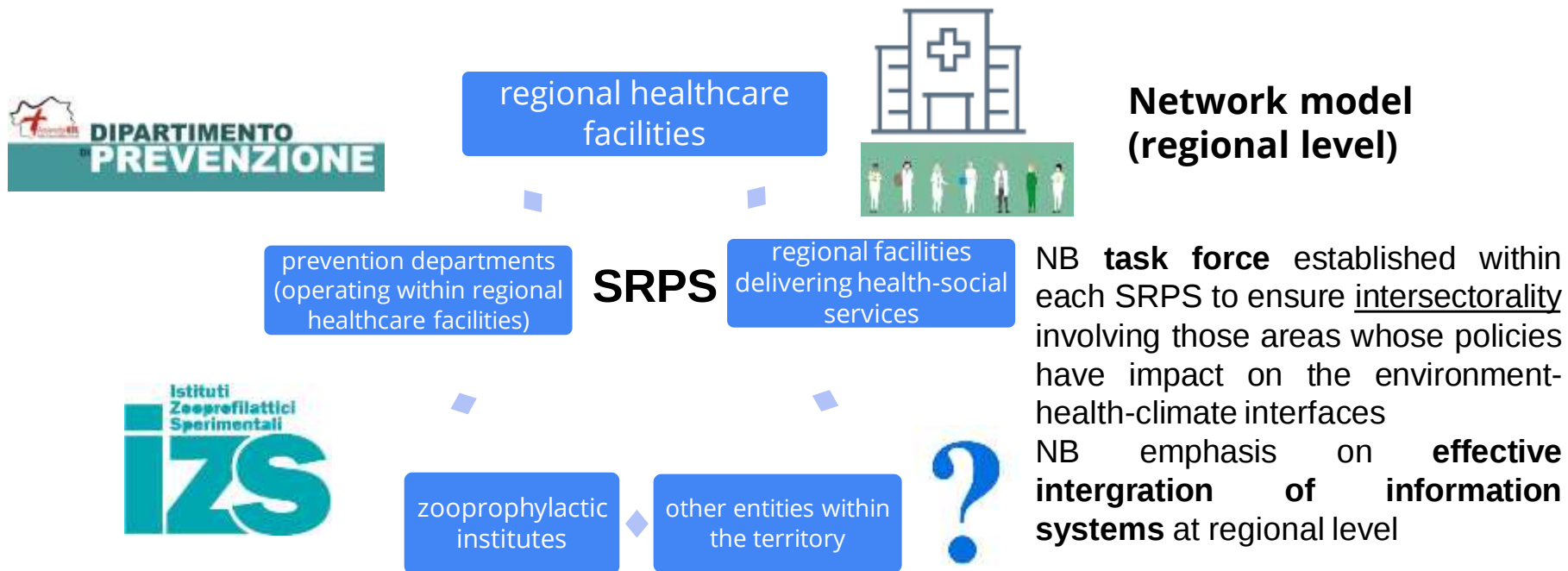
4. Fanno parte del SNPS, operando in coordinamento tra loro, in una logica di rete:

- a) i Dipartimenti di prevenzione di cui agli articoli 7 e 7-bis del decreto legislativo 30 dicembre 1992, n. 502, in coerenza con le previsioni di cui all'articolo 7-ter, comma 1, lettera b), del medesimo decreto legislativo;
- b) le regioni e le province autonome di Trento e di Bolzano, anche con funzioni di coordinamento in rete dei Dipartimenti di cui alla lettera a) tra di loro e con le altre strutture sanitarie e socio-sanitarie, nonché con gli altri enti del territorio di competenza, che concorrono al raggiungimento degli obiettivi del SNPS;
- c) gli Istituti zooprofilattici sperimentali di cui al decreto legislativo 30 giugno 1993, n. 270;
- d) l'Istituto superiore di sanità, con compiti di coordinamento e supporto tecnico-scientifico;
- e) il Ministero della salute, con compiti di indirizzo, programmazione, monitoraggio e comunicazione istituzionale, anche mediante l'adozione di apposite direttive.

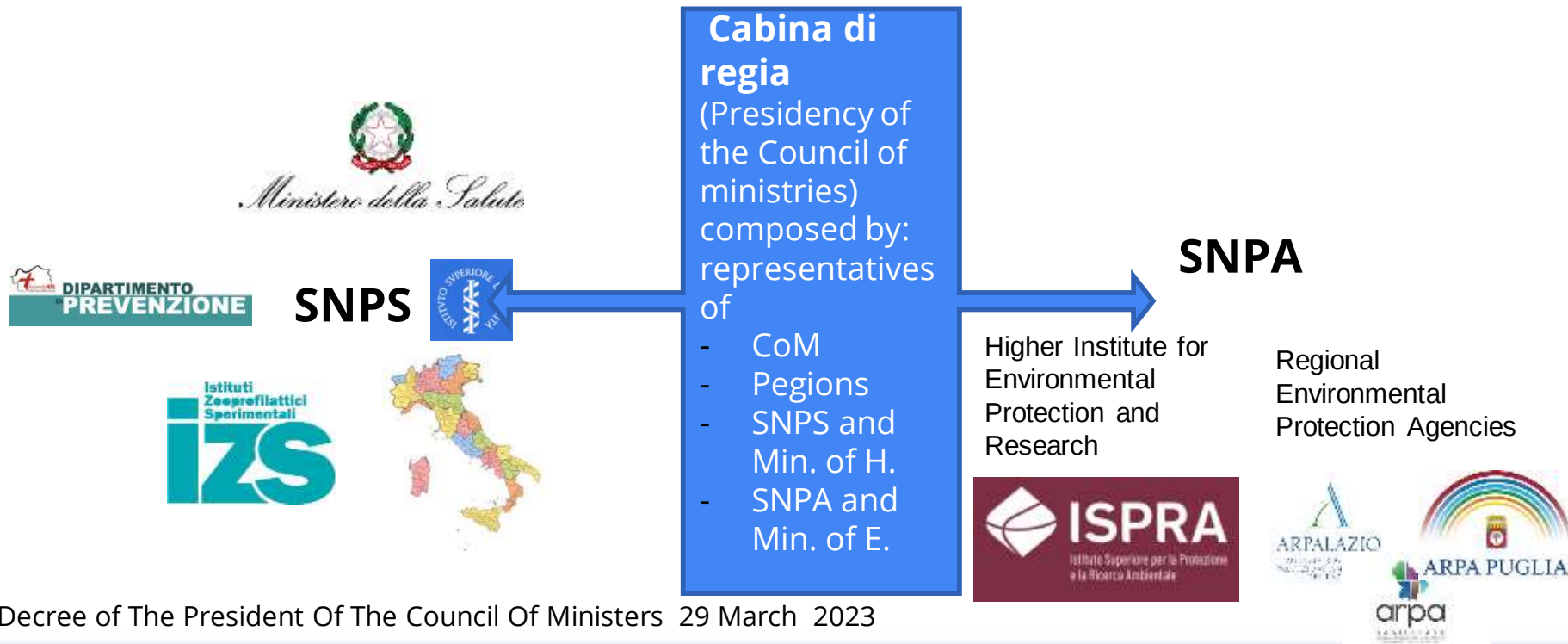
# The Structure of the National System for Preventing Health from Environmental and Climate Risks ("SNPS") (Art. 27, Decree-Law 30 April 2022, No. 36 )



# The Structure of the **Regional** System for Preventing Health from Environmental and Climate Risks ("SRPS") (Decree Ministry of Health 9 June 2022)



# The **Structure of coordination** between the National System for Preventing Health from Environmental and Climate Risks ("SNPS") and the National System for the Environmental Protection ("SNPA")



# Cabina di regia

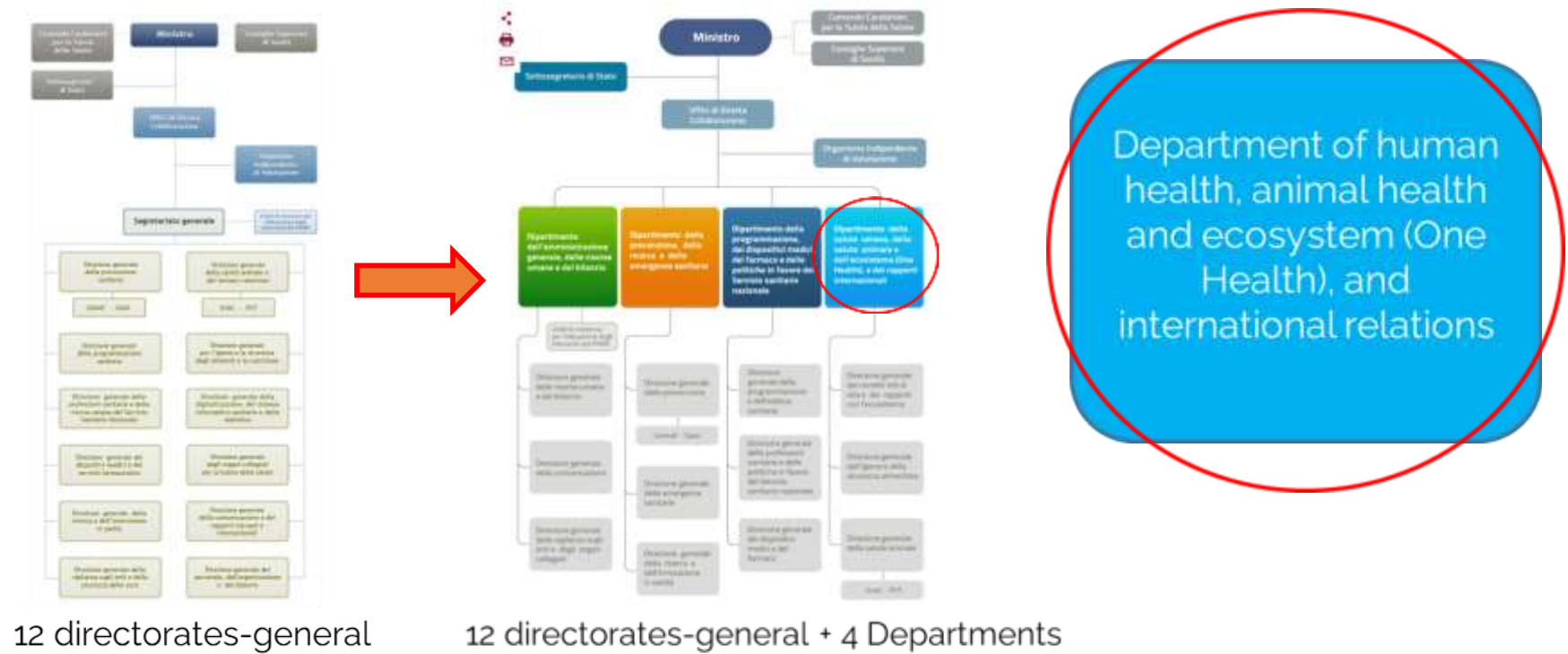
## Tasks:

- to ensure full alignment and coordination between subjects composing SNPS and the SNPA, taking on a role of **facilitator** in a logic of synergistic collaboration between institutions;
- to adopt directives aimed at promoting and harmonizing the policies and strategies implemented by the institutions that make up SNPS and SNPA, also for the purpose of **effective integration of information systems**
- to deliver the three-year **program Health, environment, biodiversity and climate, which** determines the priorities of action building on an intersectoral model «in line with the One health approach in its evolution Planetary health» (**still not adopted**)



Decree of The President Of The Council Of Ministers 29 March 2023

# 5) Decree Of The President Of The Council Of Ministers No 196 of 30 October 2023 Regulation on the organization of the Ministry of Health



## One Health as a conceptual framework

- connected with a broader dimension involving living conditions and well-being of people
- implemented in its environmental dimension and in connection with animal health and welfare (equal treatment to all pillars)
- connected to nutrition, food and nutrition education
- not fully methodologically applied

Which role for Planetary Health?  
None

# DPCM 30 ottobre 2023, n. 196 - Art. 18 Competenze

1. **Il Dipartimento della salute umana, della salute animale e dell'ecosistema (One Health), e dei rapporti internazionali**, in aggiunta alle funzioni di cui all'articolo 4 e alle attività di supporto per il Ministro nelle materie di propria competenza, provvede altresì alle attività di coordinamento e di vigilanza, anche avvalendosi del Comando Carabinieri per la tutela della Salute, in tema di:
  - a) individuazione, definizione, valutazione, informazione e promozione di corretti stili di vita, in relazione all'ecosistema, all'ambiente di vita e all'ambiente di lavoro;
  - b) esercizio delle competenze statali in materia di **nutrizione, alimenti ed educazione alimentare**;
  - c) valutazione del rischio in materia di **sicurezza alimentare**;
  - d) **salute animale**, farmaci veterinari e **benessere degli animali**;
  - e) coordinamento e finanziamento degli Istituti zooprofilattici sperimentali e vigilanza sugli stessi;
  - f) ricerca e sperimentazione nel **settore alimentare e veterinario**;
  - g) **tutela dell'ambiente e dell'ecosistema, delle condizioni di vita e di benessere delle persone**;
  - h) attuazione del decreto legislativo 9 aprile 2008, n. 8, per il personale in servizio, assegnato ovvero in posizione di distacco o comando negli Uffici veterinari per gli adempimenti comunitari (UVAC) e Posti di controllo frontaliere (PCF), per il tramite dei dirigenti titolari degli uffici;
  - i) funzioni statali in materia di **assistenza sanitaria ai cittadini italiani all'estero e di assistenza transfrontaliera**, di cui al decreto del Presidente della Repubblica 31 luglio 1980, n. 618, al decreto legislativo 4 marzo 2014, n. 38 e al decreto legislativo 25 luglio 1998, n. 286, ferme restando le competenze del Ministero degli affari esteri e della cooperazione internazionale;
  - l) coordinamento dei **rapporti con gli organismi internazionali** e della partecipazione alle relative attività e incontri a livello internazionale (Unione europea, Consiglio d'Europa, Organizzazione per lo sviluppo e la cooperazione economica, Organizzazione mondiale della sanità, Organizzazione mondiale della sanità animale, Organizzazione delle Nazioni Unite per l'alimentazione e l'agricoltura e altre organizzazioni internazionali o agenzie specializzate); **promozione della collaborazione sanitaria in ambito europeo e mediterraneo**; coordinamento e monitoraggio delle attività internazionali svolte dalle regioni in materia sanitaria; coordinamento, in base agli indirizzi del Capo del dipartimento, delle attività e delle iniziative delle Direzioni generali in materia di **progettazione, destinazione e utilizzazione dei fondi strutturali europei**;

- m) **promozione dell'attuazione delle convenzioni, delle raccomandazioni e dei programmi comunitari e internazionali in materia sanitaria**; svolgimento delle attività connesse alla stipula degli accordi bilaterali o multilaterali del Ministero in materia sanitaria, ivi compresi, in raccordo con la Direzione generale di cui all'articolo 15, quelli europei ed internazionali in tema di assistenza sanitaria;
- n) supporto tecnico in ambito sanitario al Ministero degli affari esteri e della cooperazione internazionale e all'Agenzia italiana per la cooperazione allo sviluppo e, ferme restando le competenze di questi, coordinamento delle attività di programmazione e di indirizzo svolte dal Ministero della salute ai fini dell'elaborazione di linee strategiche sulla salute globale e sulla politica sanitaria internazionale dell'Italia;
- o) cura del contenzioso e affari legali nelle materie di competenza del Dipartimento;
2. Il Dipartimento esplica le funzioni spettanti al Ministero quale Autorità nazionale di riferimento **dell'Autorità europea per la sicurezza alimentare**, avvalendosi della Direzione generale dei corretti stili di vita e dei rapporti con l'ecosistema, **cura i rapporti con la World Organisation for Animal Health (WOAH) e la Food and Agriculture Organization (FAO)** e, per le materie di competenza, con l'Unione europea, il Consiglio d'Europa, **l'Organizzazione mondiale della sanità e le altre organizzazioni internazionali**.
3. Nell'ambito del Dipartimento opera il **Centro nazionale di lotta ed emergenza contro le malattie animali** di cui all'articolo 5 del decreto legislativo 5 agosto 2022, n. 136.
4. Il Capo del Dipartimento della salute umana, della salute animale e dell'ecosistema (One Health), e dei rapporti internazionali svolge le funzioni di **Capo dei servizi veterinari italiani - Chief Veterinary Officer (CVO) nelle istituzioni europee ed internazionali**, nonché le funzioni di presidente del Centro nazionale di lotta ed emergenza contro le malattie animali e delle rispettive articolazioni, ai sensi dell'articolo 5, commi 3 e 4, lettera a), del decreto legislativo 5 agosto 2022, n. 136, ove in possesso della professionalità medico-veterinaria. Qualora non ricorra tale condizione, il Ministro conferisce le anzidette funzioni a un direttore generale del Ministero in possesso della predetta professionalità.

# 6) Constitutional Law No. 1 of 11 February 2022 'Amendments to Articles 9 and 41 of the Constitution on environmental protection'.

## Is There One Health?

*fundamental principles*

Art. 9

The Republic shall promote the development of culture and of scientific and technical research. It shall safeguard the natural beauties and the historical and artistic heritage of the Nation. **It shall safeguard the environment, biodiversity and ecosystems**, also in the **interest of future generations**. State law shall regulate the methods and means of safeguarding **animals**.

Art. 41

Private economic enterprise shall have the right to operate freely. It cannot be carried out in conflict with social utility or in such a manner as may harm **health, the environment**, safety, liberty and human dignity. The law shall determine appropriate programmes and checks to ensure that public and private economic enterprise activity be directed at and coordinated for social **and environmental** purposes.

*negative constraints («produce, but do no harm to health and environment»)*

*paves the way for positive obligation («produce to improve the environment») economic steering by the public authorities*



# Conclusive remarks

## Pathways to move forward

### Is it enough?

- gaps from a conceptual perspective -> embrace the **more comprehensive definition** of One Health put forward by the OHHLEP and better evaluate relations with Planetary health
- gaps from an organisational perspective -> **interinstitutional integration** (Ministry of Health and....?; improve experience as the SNPS-SNPA cooperation)
- gaps from a methodological perspective -> **shared governance** and **inclusiveness** (all segments of society, academia, and the private sector) to build public consensus



### Moving forward with One Health lens

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# Essential bibliography



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