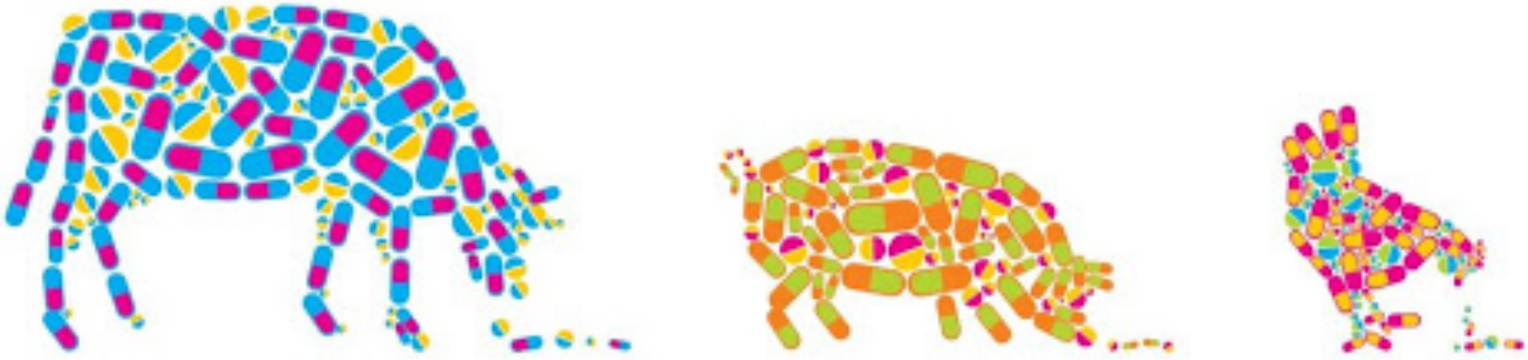
ANTIMICROBIAL RESISTANCE: GOVERNANCE, RISK REGULATION AND INTERNATIONAL TRADE



MASTER THESIS: LAVINIA SCUDIERO

SUPERVISOR: DR. ALEXIA HERWIG

Wageningen University and Research, September 2020

Master thesis Food Safety Law

Antimicrobial Resistance: Governance, Risk Regulation and International Trade

Academic year: 2019-2020

Defence day: 28 September 2020

Submitted by: Lavinia Scudiero

Student number: 931004756240

Code: Law-80436

Study programme: MSc Food Safety - Food Law and Regulatory Affairs

Department: Law and Governance

Supervisor: Alexia Herwig

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AMR: Antimicrobial Resistance

AMU: Antimicrobial Use

ALOP: Appropriate Level of Protection

ASF: Animal Sourced Products

CAC: Codex Alimentarius Commission

CDC: Centre for Disease Control and Prevention

COVID-19: Coronavirus Disease

FAO: Food and Agriculture Organization

GATT: General Agreement on Tariffs and Trade

GASL: Global Agenda for Sustainable Livestock

GDP: Global Gross Domestic Product

LAMP: Livestock Antimicrobial Partnership

LMICs: Low-Income and Middle-Income Countries

NAP: National Action Plan

OIE: World Organization for Animal Health

SPS: Agreement on Sanitary and Phytosanitary measures

TATFAR: Transatlantic Taskforce on Antimicrobial Resistance

TBT: Agreement on Technical Barriers to Trade

TFAMR: Codex Task Force on Antimicrobial Resistance

VMP: Veterinary medicinal products

WHO: World Health Organization

WTO: World Trade Organization

ABSTRACT

Although antimicrobial treatments have a crucial role in modern medicine, they are also essential tools for veterinary care and agricultural practices. With the intensification of global food production over the past century, the use of antimicrobials has grown exponentially, and with an ever-growing demand of high value protein from animal products, it is not expected to decrease. The abuse and misuse of the drugs in health care and agricultural services has led to the rapid development of antimicrobial resistance (AMR) (which per se is a natural phenomena), making treatments against dangerous infectious diseases with pandemic potentials ineffective. Beside the uncontrolled use of antimicrobials, evidence suggests that international and interconnected livestock food chains play as additional drivers for the development of the issue. The interrelated and complex chains pose dire risks to global health, the environment and socio-economic stability, hampering substantially the efforts towards sustainable development. In light of the important challenge, the optimization of antimicrobial use to achieve economic growth, reduce hunger and protect the global health has become a matter of urgency that requires effective governance and risk regulation. While multilateral organizations with the Tripartite Organization on AMR are struggling to find fit-for-all answers because of major disagreements among the mandates of the different organizations and diverse interests of the countries, unilateral measures at country level are materializing posing a threat to free trade and debates within the Word Trade Organization (WTO) disciplines. Furthermore, mulstistakheolder partnerships with civil societies, public and private parties are starting to emerge to find holistic solutions and spread public awareness on AMR. The present thesis investigates the potential relation between the three emerged governance approaches and relative regulation instruments to AMR in all its policy domains and WTO law, with the aim to tentatively determinate the mechanism that would best safeguard global health as well as trade interests.

PART I INTRODUCTION

I.I Background

Antibiotics have marked an important turnover in the history of humankind, science and modern medicine. Since their discovery in the 20th century, not only they have facilitated the treatment of communicable diseases that for centuries have been threatening human's health and survival, but they also have modernized developments in areas of medicine that in the past were highly susceptible to complications[1]. The term antibiotic refers to both natural and synthetic molecular substances with properties to kill or inhibit the growth and multiplication of lethal microorganisms for people, animals and plants[2]. These innovative medicines were firstly introduced in hospitals in 1930[3], and subsequently with research and innovation, the scientific community rapidly understood that their potentials could go far beyond the human medicine domain. Evidencing the effects of the drugs also at agricultural and animal husbandry level, the chemical compounds rapidly became considered essential resources for the fast production of high quantity of food improving considerably farming efficiency practices [4]. Nowadays, antibiotics are largely used as veterinary drugs to treat animal diseases, and in some countries, as growth promoters to increase the output of animal farming as well as in agriculture to prevent and control infections and improve feed efficiency[5]. Antibiotics have hence rapidly changed the way of practising agriculture and helped in tackling the problem of producing enough food for an ever-growing human population.

With more than 9 billion people living on heart by 2050, an estimated 70%[6] increase of food demand is expected. Animal sourced food (ASF), which presents important nutritional values, has the potential to contribute in a considerable way to meet the requirements of this growing demand. It is expected that the world will demand up to 50%[7] more ASF to nourish everybody, providing the livestock sector with an opportunity to contribute to the global socio-economic growth of societies and human well-being, as well as trade liberalisation for agricultural products with high value nutritional components. This important contribution however has to deal with the challenge to provide larger quantity of high quality and affordable products without leaving implications for the environment and future generations. As such, while the sector is beneficial for many aspects of sustainable development, it also

[1] WTO (2016). NEWS: SPEECHES — DG ROBERTO AZEVÊDO. Retrieved from https://www.wto.org/english/news_e/spra_e/spra142_e.htm (accessed August 26, 2020)
[2] Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2
3 Ibidem
[4] Economou V., Gousia P. (2015). Agriculture and food animals as a source of antimicrobial-resistant bacteria, Dove Medical Press, pp.49-61.
[5] Ibidem
[6] FAO (2009). Global Agriculture Towards 2050.
[7]Ibidem

produces a number of negative externalities: livestock is currently the largest user of natural resources, livestock contributes to the 14.5%[8] of global greenhouse gas emissions and livestock production contributes to the spreading of existing and new infectious diseases, some with zoonotic and pandemic potentials. Ultimately, the overuse of veterinary medicinal products is thought to contribute the development of antimicrobial resistance (AMR).

In fact, in spite of the medical and production benefits, it has become immediately clear that thoughtless use of antibiotics (AMU) could lead to the rapid evolution of resistant pathogens[9]. Already in 1945, Fleming, the discoverer of penicillin, stated in an interview "In such cases, the thoughtless person playing with penicillin is morally responsible for the death of the man who finally succumbs to infection with the penicillin resistant organism. I hope this evil can be averted."(New York Times, 1945), evidencing the fact that the medicines had to be handled with precaution if they wanted to be preserved[10].

Now the scientific community refers to the issue with the concept of AMR[11], or the mechanisms that dangerous resistant bacterial pathogens or 'superbugs' develop to grow in the presence of antibiotic medicines. More in specific, AMR designates the ability of a pathogenic microorganism -being a given bacteria, virus, fungi- to create survival advantages and tolerate first choice antimicrobial treatments that would normally kill them or limit their growth[12]. Three basic types of AMR are described in the literature: intrinsic, acquired, and adaptive. Intrinsic resistance entails all of the natural genetic characteristics of a microorganism that can limit the action of a given antibiotic. The acquired resistance turns the microorganism resistant to the molecules through the incorporation of new genetic materials or because of genetic mutations. The organisms are able to grow, adapt and subsequently proliferate in any new and dynamic environment and able to transmit the resistant genetic information to subsequent generations of organisms[13].

The third type of AMR is defined as the ability of the microbes to acquire adaptive resistant capacity modifying spontaneously its genetic transcription through mutability in the target genes and a binding genetic plasticity, which in turn enable the horizontal transfer of mobile genetic elements among microorganisms[14]. This happens very quickly and only when there is a changing environment such as a change in an antimicrobial compound, ion densities and temperature or a long exposure to non-lethal doses of antibiotics subinhibitory concentrations in specific medical practices (e.g. prevention practices of diseases in animal farming). Unlike the other two types of resistance, the adaptive occurs

[8] Gerber, P.J., Steinfeld, H., Henderson, B., Mottet, A., Opio, C., Dijkman, J., Falcucci, A. & Tempio, G. (2013). Tackling climate change through livestock – A global assessment of emissions and mitigation opportunities. Food and Agriculture Organization of the United Nations (FAO), Rome.
[9] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[10] Ibidem
[11] WHO. "resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it"
[12] Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2
[13] Salimiyan Rizi, K. K., & Noghondar, M. (2018). Adaptive antibiotic resistance: Overview and perspectives. J. Infect. Dis. Ther, 6, 1-3.
[14] Ibidem

only in the presence of antibiotics [15]. However, recent findings suggest that DNA sequence alone do not explain fully the development of AMR, rather nonclassical mechanisms like bacterial epigenetic may also have a role in the development of resistance[16].

During the dissemination of AMR, in the first-place pathogens develop a *de-novo* mutation and/or acquisition of resistance genes via mobile genes that can rapidly spread through subsequent bacterial populations, like with plasmids mediating an antimicrobial-resistance phenotype. Consequently, resistant strains adapt through time in the environment. It is now understood that several vectors allow bacterial plasmids and clones to be transported between different environments, such as human beings, insects, animals, agricultural practices and water, bringing implications for society as a whole[17][18][19]. While the resistance is a natural occurring phenomenon, the imprudent use and excessive consumption (later explained) of antibiotics has accelerated its development, being its main driver the practice of over prescriptions and below standards infection controls at health sector level[20][21]. Especially, an increasingly highlighted important role is played by mass medication of animals with antimicrobials that are critically important for humans, such as third generation cephalosporins and fluoroquinolones, and in more the long-term mixed in-feed for growth promotion, colistin, tetracyclines, and macrolides[22].

Residues of drugs can remain in the final products and their waste[23], which compromise the safety of food and the environment and further expose humans and animals to the development of chronic resistances[24]. The transfer of these pathogens to human beings in the food sector can occur through several routes being the direct contact between animals and humans, notably among livestock keepers and veterinarians, the most evident[25]. Other described interactions seem to happen all along the food chain: from the slaughtering of the animals through the processing, transportation, storage and consumption at consumer level. In addition, in the spread of resistant bacteria, also animal manure

[15] Ibidem
[16] Ghosh, D., Veeraraghavan, B., Elangovan, R., & Vivekanandan, P. (2020). Antibiotic resistance and epigenetics: more to it than meets the eye. Antimicrobial agents and chemotherapy, 64(2).
[17] O'Neill J. (2016). Tackling drug-resistant infections globally: final report and recommendations— the review on antimicrobial resistance. Retrieved from https://amrreview.org/sites/default/files/160525_Final%20paper_with%20cover.pdf (accessed August 26, 2020).
[18] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[19] Von Wintersdorff, C. J., Penders, J., Van Niekerk, J. M., Mills, N. D., Majumder, S., Van Alphen, L. B., ... & Wolffs, P. F. (2016). Dissemination of antimicrobial resistance in microbial ecosystems through horizontal gene transfer. Frontiers in microbiology, 7, 173.
[20] Holmes AH, Moore LS, Sundsfjord A, et al (2016). Understanding the mechanisms and drivers of antimicrobial resistance. Lancet; 387: 176–8
[21] WHO. Antimicrobial resistance. (2018). www.who.int/mediacentre/factsheets/fs194/en/ (accessed August 26,2020)
[22] McEwen, S. A., & Collignon, P. J. (2018). Antimicrobial resistance: a one health perspective. Antimicrobial Resistance in Bacteria from Livestock and Companion Animals, 521-547.
[23] Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH.
[24] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO.
[25] Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2

seems to play a role. The manure is in fact used as fertilizers that can contaminate vegetable food products and also the environment and the water with waste residues[26] .
Evidence suggests that the quantity of antibiotics in animal husbandry, especially in meat production, is comparable or greater to quantity implemented in human medicine[27]. Just in the EU for instance about two thirds of total AMU is for food producing animals[28]. However, overall, still very little is known about the exact global AMU in food because of poor surveillance methods and few data available on different settings and conditions like animal species, geographical regions, domestic regulations, intensity of production and sales intentions [29]. What seems clear however is that unprecedented global interactions result of human progress, such as travels, migration and trade integration[30] (and globalisation and international travels mean more people being vectors) extremely facilitated the process of AMR. Additionally, although the AMU at medical level keeps being designated as the primary driver of the emergence and maintenance of AMR, other factors such as governance quality, corruption, public spending on health, poverty, below standard infrastructures, poor education, poor waste controls and changing climate conditions also contribute to its increased prevalence [31].

The scientific community has been left with little margin of action for fast and effective solutions against the rapid issue; new drug development programmes and research in fact seem insufficient to provide effective therapeutic alternatives as a new drug need in average at least from 10 to 20 years to be developed [3233]. In addition, for the last 30 years very few novel molecules have been discovered[34]. The not too distant future has been described as apocalyptic in terms of consequences, with relatively low hopes for the effective prevention of risk complications for many ordinary medical practices such as chemotherapy and organs transplant, and treatment of well-known, and in many places eradicated, diseases such as pneumonia and tuberculosis [3536]. A growing number of studies have shown that higher rates of infections with resistant bacteria are associated with increased medical complications, hospitalization rates, more expensive treatments and growing cases of mortality and morbidity[3738].

[26] Ibidem
[27] O'Neill J. (2015). Antimicrobials in agriculture and the environment: reducing unnecessary use and waste, Review on Antimicrobial Resistance, p. 1
[28] European Court of Auditors (2019). Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU.
[29] Bengtsson, B., & Greko, C. (2014). Antibiotic resistance—consequences for animal health, welfare, and food production. Upsala journal of medical sciences, 119(2), 96-102.
[30] O'Neill J. (2016). Tackling drug-resistant infections globally: final report and recommendations— the review on antimicrobial resistance. Retrieved from https://amrreview.org/sites/default/files/160525_Final%20paper_with%20cover.pdf (accessed August 26, 2020).
[31] Collignon, P., Beggs, J. J., Walsh, T. R., Gandra, S., & Laxminarayan, R. (2018). Anthropological and socioeconomic factors contributing to global antimicrobial resistance: a univariate and multivariable analysis. The Lancet Planetary Health, 2(9), e398-e405.
[32] Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH
[33] Kumarasamy, K. K., Toleman, M. A., Walsh, T. R., Bagaria, J., Butt, F., Balakrishnan, R., ... & Krishnan, P. (2010). Emergence of a new antibiotic resistance mechanism in India, Pakistan, and the UK: a molecular, biological, and epidemiological study. The Lancet infectious diseases, 10(9), 597-602.
[34] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[35] Cahill, S. M., Desmarchelier, P., Fattori, V., Bruno, A., & Cannavan, A. (2017). Global perspectives on antimicrobial resistance in the food chain. Food Protection Trends, 37(5), 353-360
[36] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One Health, 5, 6.
[37] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO.

These issues are further integrated to social and personal costs because of increased suffering, disability and illness, time off work and interference with social activities[39]. Experts have warned that the costs to human beings because of the loss of the therapeutic effectiveness of antimicrobials, in the long term will reverse the benefits of the short-term efficiency gains in fast recoveries [40], posing a critical health challenge.

The World Health Organization (WHO) estimated that 33 000 people die in the world each year[41] because of infectious diseases caused by resistant microbes, being just 25000 Europeans[42]. In addition, the Food and Agriculture Organization (FAO) predicts that by 2050 approximately 10 million human fatalities will be expected annually because of the issue[43]. Experts have evidenced also the financial and social costs to society estimating additional yearly costs of €1.5 billion [44] due to extra health care losses, the reduction on countries income and productivity losses[4546]. The World Bank warned that the damage to the global economy could be comparable to the 2008 global financial crisis [47] and another study conducted by the FAO expects a 2 to 3.5 per cent decrease in global Gross Domestic Product (GDP) [48], with low-income and middle-income countries (LMICs) previewed to be hit the hardest [49].

Likewise, human medicine, where antibiotics help treating diseases in a more cost-effective way in respect to other treatments [50], at farming level the over the counter and inappropriate AMU finds its explication because the practice allows optimizing on animal production inputs. For instance, investing more into antibiotics in the short term helps in the reduction of expenses for maintaining nutritional and hygienic high standard practices, while keeping the production rate considerably efficient[51]. Imprudent (or inappropriate) practices of antimicrobials occur when the drugs are used in not needed occasions, meaning implemented at inappropriate times, or at the inappropriate dose

[38] Collignon, P. (2015). Antibiotic resistance: are we all doomed?. Internal medicine journal, 45(11), 1109-1115.
[39] Ibidem
[40] Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH
[41] European Court of Auditors (2019). Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU
[42] WHO, Regional Office for Europe (2011). Tackling antibiotic resistance from a food safety perspective in Europe, p. xiii.
[43] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO
[44] European Court of Auditors (2019). Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU
[45] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO
[46] Collignon, P., Beggs, J. J., Walsh, T. R., Gandra, S., & Laxminarayan, R. (2018). Anthropological and socioeconomic factors contributing to global antimicrobial resistance: a univariate and multivariable analysis. The Lancet Planetary Health, 2(9), e398-e405.
[47] Inoue, H., & Minghui, R. (2017). Antimicrobial resistance: translating political commitment into national action. Bulletin of the World Health Organization, 95(4), 242.
[48] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO
[49] World Bank (2016). Drug-resistant infections: a threat to our economic future (discussion draft). Retrieved from: http://pubdocs.worldbank.org/en/527731474225046104/AMRDiscussion-Draft-Sept18updated.pdf (accessedAugust 26, 2020).
[50] European Court of Auditors (2019). Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU
[51] Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH

recommendation (frequency and duration) or with the wrong disease [52]. In animal farming, a common example of imprudent practice is the non-therapeutic use of small doses of antimicrobials in feed as a prophylactic measure in healthy animals to prevent the spread of diseases or to promote the growth of the stocks[53]. In addition, inappropriate practices include factors such as the failure to notice and stick to withdrawal periods and labels recommendations, wrong prescriptions, over the counter sales and defective treatment records. In addition, the continuous pollution of the environment, a general lack of regulations or their enforcement and government commitment, together with low consumers' awareness about the magnitude of health hazards and costs, are all additional factors that contribute to antibiotic residues and resistance in food products[54][55]. In fact, as per the World Organization for Animal Health (OIE), currently out of 130 counties, not even the 85% have implemented regulations for imports, production and distribution of veterinary medicines[56].

Because essential tools to preserve animal life, welfare and therefore secure food and incomes[57], antibiotics are unavoidable, and a non-use scenario is to be considered as utopic. Giving up on their potential would in fact lead to animal welfare and heath challenges, as animal organisms need treatments too[58]. Additionally, avoiding AMU in feed would reduce its quality and safety, which in turn would lead to a decrease in animal production efficiency[59]. However, the consequences of misuse of AMR can provoke therapy failures having a similar negative effect on animal health as when not using antibiotics, and therefore directly leading to similar socio-economic losses. These would represent financial losses for producers because of higher mortality and decreased feed conversion, reduced production, and growth of animals, emotional stress for animals' keepers [60] [61] and higher costs of commodities for the end consumers. For instance, by 2050 a study of the World Bank foresees 11% losses of livestock production just in LMICs and a 1.1% to 3.8% fall of global exports[62]. Hence, while it is undeniable that antibiotics are and will remain vital to treat infections and avoid animal suffering, reducing inappropriate antibiotic consumption and finding ways to use the drugs in a sustainable manner, meaning protecting animal and human health while at the same time securing production

[52] WHO Regional office for Europe retrieved from: https://www.euro.who.int/en/about-us/whd/past-themes-of-world-health-day/world-health-day-2011-antibiotic-resistance-no-action-today,-no-cure-tomorrow/antibiotic-resistance/frequently-asked-questions (accessed August 26,2020)
[53] Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2
[54] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO
[55] Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH
[56] OIE (2016). OIE annual report on the use of antimicrobial agents in animals. Better understanding of the global situation.
[57] Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2
[58] FVE (2016). Relationship between animal welfare and the use of antibiotics in food animals. doc/063. Retrieved from https://www.fve.org/cms/wp-content/uploads/063-FVE_AWW-Position-on-resistance-and-animal-welfare_final.pdf (accessed August 26, 2020)
[59] FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO
[60] Vaarten J. (2012). Clinical impact of antimicrobial resistance inanimals. Rev Sci Tech. 31:221–9.
[61] Bengtsson, B., & Greko, C. (2014). Antibiotic resistance—consequences for animal health, welfare, and food production. Upsala journal of medical sciences, 119(2), 96-102.
[62] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32

income and food for everybody is a globally recognised multi policy priority.

As such, animal sourced products (ASF) are an important and essential source of nutritional micronutrients and minerals for the human diet and play a pivotal role in the fight against food and financial insecurity, especially in times of increasing spikes on demand of ASF. Because of the growth in human population, which is expected to reach 9 billion by 2050[63], major ASF commodities such as meat, milk, and eggs from conventional livestock and fish in aquaculture will contribute substantially to reduce the issue of under nutrition[64]. In addition, non-conventional livestock such as camels, horses and bees are locally and regionally important for the production of food, employment and for the improved livelihoods[65]. However, with intensive production practice to meet the growing demand of products which is expected to rise by two-third before 2030, it is clear that livestock farming in parallel is contributing also to negative outcomes, most notably climate change because of enteric greenhouse gas emissions and threats to public health with zoonosis and AMR with pandemic potentials [66].

Especially, as the coronavirus disease (COVID-19) blisters its way around the globe, and hundreds and thousands of lives have been lost and the global economy paralysed, much of the scientific and public focus has now strongly shifted on the unhealthy relationship that modern food systems have with animals[67]. Even though COVID-19 does not seem to find its origin in livestock and livestock does not transmit the disease to humans, current evidence suggests that the diseases emerged from an animal source[68], which brought the issue of zoonosis and human-animal health interface high on the global political landscape priorities.
The WHO stated, "The greatest risk for zoonotic disease transmission occurs at the human-animal interface through direct or indirect human exposure to animals, their products and/or their environments"[69] and the Disease Control and Prevention (CDC) found that approximately three on four new emerging disease for human beings are of animal origin[70].The COVID-19 has awakened globally the effects of a pandemic on human beings normal life, and as a result, the public is posing

[63] FAO (2018). The future of food and agriculture, alternative pathways to 2050. Retrieved from http://www.fao.org/3/I8429EN/i8429en.pdf (accessed August 26,2002)
[64] FAO (2012). FAO Statistical yearbook 2013: World Food and Agri-culture. Rome: Food and Agriculture Organization of theUnited Nations. Retrieved from http://www.fao.org/docrep/018/i3107e/i3107e00.htm. (Accessed August 24, 2020)
[65] Bengtsson, B., & Greko, C. (2014). Antibiotic resistance—consequences for animal health, welfare, and food production. Upsala journal of medical sciences, 119(2), 96-102.
[66] O'Neill J. (2015). Antimicrobials in agriculture and the environment: reducing unnecessary use and waste, Review on Antimicrobial Resistance, p. 1
[67] The Hill (2020). Reducing pandemic risk begins with ending factory farming. Retrieved from https://thehill.com/opinion/energy-environment/491066-reducing-pandemic-risk-begins-with-ending-factory-farming
(accessed August 26,2020)
[68] OIE. Covid-19 portal. Retrieved from https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/
(accessed 26 August, 2020)
[69] WHO. Zoonoses. Retrieved from https://www.who.int/zoonoses/en/
(accessed August 24, 2020)
[70] CDC. Zoonotic diseases. Retrieved from https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html
(accessed August 24, 2020)

questions as whether there is a political and cultural will to decrease the likelihood of other possible bacterial pandemics from antibiotics ineffectiveness .

Expansion of human population, modern models of capital-intensive agribusiness and the disruption of ecosystems in recent decades are increasingly addressed as the principal driver of zoonotic diseases and AMR[71]. The capital- intensive system most of the time includes overcrowded farming facilities with below standard animal welfare conditions that enable fertile grounds for the spreading of pathogens among animals. These can easily spill over to the human species and result in epidemics or pandemics thanks to the modern and interconnected society of nowadays[72]. The scientific community has long issued warnings about the potential threats to human health of modern intensive livestock farming, announcing several times the imminence of disastrous pandemics as well as foreseeing in the near future a post-antibiotic era[73].
While the scientific community agrees that fast action must be taken, the public and advocacy groups advocate for more radical measures and changes in order to address the root of the problem. For instance, investing in more natural resilient food systems that move towards smaller herds and put less stress on both animals and the environment. As well as a type of agriculture that relies less, or avoid at all, the use of chemicals and drugs .The complex interdependent human, animal, environmental dimensions of AMR, together with its multi-sectorial and trans-boundary potentials, shifted the issue from being considered a public health only concern to a so-called One Health one[7475]. The One Health approach recognises that holistic efforts at every sector involved in the issue, are needed for the preservation of the continued effectiveness of antimicrobials. It further includes the collaboration of multiple professions and stakeholders to attain simultaneously optimal health for people domestic animals, wildlife, plants, and the environment[76]. These multidrug-resistant organisms that find fertile multi-environments to develop, have shown to spread rapidly to other geographical locations and spill over into other species (animal-animal and human-animal), dramatically increasing the danger of the treat and therefore requiring a strong cooperation to be solved.

At international level, several actions have been taken throughout the last two decades trying tackle the issue. These include for instance the first WHO resolution on AMR, the establishment of a

[71] The Guardian (2020). Is factory farming to blame for coronavirus? Retrieved from https://www.theguardian.com/world/2020/mar/28/is-factory-farming-to-blame-for-coronavirus (accessed August 26, 2020)
[72] The Hill (2020). Reducing pandemic risk begins with ending factory farming. Retrieved from https://thehill.com/opinion/energy-environment/491066-reducing-pandemic-risk-begins-with-ending-factory-farming
(accessed August 26,2020)
[73] Centres for Disease Control and Prevention (US). (2019). Antibiotic resistance threats in the United States, 2019. Centres for Disease Control and Prevention, US Department of Health and Human Services. Retrieved from https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
(accessed August 24, 2020)
[74] Collignon, P., Beggs, J. J., Walsh, T. R., Gandra, S., & Laxminarayan, R. (2018). Anthropological and socioeconomic factors contributing to global antimicrobial resistance: a univariate and multivariable analysis. The Lancet Planetary Health, 2(9), e398-e405
[75] McEwen, S. A., & Collignon, P. J. (2018). Antimicrobial resistance: a one health perspective. Antimicrobial Resistance in Bacteria from Livestock and Companion Animals, 521-547.
[76] Ibidem

Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) which encouraged global research on AMR [77], an international agreement on the One health approach which includes the coordination across sectors, the development of a WHO Global Action Plan that demanded countries to develop a National Action Plan (NAP) programme by 2017 and the endorsement from G20 leaders to establish a new collaboration on research and development of new antimicrobials [78]. These have been strongly promoted by countries such as Sweden and the Netherlands that are a champion on the control of AMR and where AMU reduction has been successfully evidenced through improved animal husbandry practices[79].

Despite these efforts however, evidence shows that if the threat of superbugs led governments to recalibrate policies and regulate the use of the drugs in human medicine, little attention has been shown for the other key slowing emerging aspect of AMR, which is the inappropriate AMU in animal and food production[80]. As a matter of fact, the tripartite collaboration of the WHO, FAO and OIE, established to promote cross-sectorial collaboration to address risks from zoonoses and other public health threats, reported that in 2017 only 51% of the countries developed a NAP, being the rest still in the process of the establishment[81], showing that the One Health approach is far from being consolidated. Effective and availability of antimicrobial treatments for everybody is part of the global commons, so containment of AMR can be considered a global public good. Once it is achieved, all countries will enjoy the benefits of antimicrobials availability. At the same time, all countries will be harmed if AMR is not tackled[82].

The lack of will from national policy makers to take fast actions for a public good seems to be caused by the unclear scientific evidence on the role of food products as direct transmission routes of AMR to humans. In fact, the data on the matter are generally contested or felt as not sufficient [83]. In addition to that, countries are not politically nor economically prepared to take effective actions[84], especially LMICs where substantive finances and expertise are missing[85]. However, the recent discovery of the development of resistance in food producing animals, humans, pets and food to the WHO's critically important antimicrobial colistin in over 30 countries, might have changed the scenario and unblocked this general political inertia[86]. The discovery in fact has shown that international food chain

[77] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[78] Ibidem
[79] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.
[80] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.
[81] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[82] Adeyi, O. O., Baris, E., Jonas, O. B., Irwin, A., Berthe, F. C. J., Le Gall, F. G., ... & Shriber, D. E. (2017). Drug-resistant infections: a threat to our economic future. World Bank Group, Washington, DC.
[83] Bennani, H., Mateus, A., Mays, N., Eastmure, E., Stärk, K. D., & Häsler, B. (2020). Overview of evidence of antimicrobial use and antimicrobial resistance in the food chain. Antibiotics, 9(2), 49.
[84] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.
[85] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[86] George, A. (2019). Antimicrobial Resistance (AMR) in the Food Chain: Trade, One Health and Codex. Tropical Medicine and Infectious Disease, 4, 54

production and integration might play an evident role in the spreading of AMR, making the issue more politically sensitive with significant potentials to underpin trade policies and national interests [87].
The COVID-19 pandemic for instance is making evident the nexus between food, hunting, husbandry and trade at the global level which facilitated a minor local issue becoming rapidly into a global one of extreme magnitude because global legal governance framework let the risk proliferate.
While international effort have been called to make collaboration stronger to support national governments on the implementation of national strategies on coherent management of AMR [88], and Codex Alimentarius Committee has been delegated to review its AMR policy standard framework (expected to be finalized not before the end of 2020) as a way to harmonize countries and regulation, the European Union (EU) alone has also taken actions. Following the priorities of its One Health approach, in 2018 the Union agreed on implementing two new legislations: Regulation 2019/06 on Veterinary Medicinal Products (VPMs) and Regulation 2019/04[89] on Medicated Feed[90] (VMP package). The regulations that envisage stricter measures on antibiotics handling at animal husbandry level have already become object of critiques from trade partners[91], which feel the measures as potential trade barriers in the context of the World Trade Organization (WTO) disciplines, especially the Sanitary and Phytosanitary (SPS). The harsh words of Dr. P. Parker, president of the Australian Veterinary Association, perfectly resumes the overall global feeling towards EU's decision: "health of Australian animals should not be dictated by Brussels, and farmers and veterinarians should not be put in the position of potentially having to select an inferior therapy to maintain market access"[92]. The EU has been called to reconsider that EU countries alone cannot coordinate their actions in isolation from the rest of the global community because AMR is an issue that does not respect borders given its multi transmission and difficult to control channels[93].

Minimizing the development of AMR is a complex priority that needs to be addressed in a sustainable and systematic- thinking way in all its risk interactions. Complex sustainable issues and public good problems such as AMR require collective action from all actors of the sector and countries for effective solutions. In this context, multi stakeholder networks and forums are currently being perceived as a new and innovative way of governance approach[94]. In fact, this approach includes the concept that different interest groups that work across different sectors and scales of society can share a common

[87] Ibidem
[88] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[89] EU (2018). Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed repealing Council Directive 90/167/EEC
[90] EU (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.
[91] Ad Hoc Codex. Intergovernmental Task force on Antimicrobial Resistance (2018). Matters Arising from Other Relevant International Organizations (OECD, World Bank, World Customs Organization, WTO). Retrieved from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F% 2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-06%2FWD%2Famr06_04e.pdf (accessed August 26, 2020)
[92] EURONEWS (2018) New EU rules will force Australian farmers to choose between treatment or trade. Euronews.com. last access 03/04/2020
[93] WHO (2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32
[94] Brouwer, J. H., Woodhill, A. J., Hemmati, M., Verhoosel, K. S., & van Vugt, S. M. (2015). The MSP guide: How to design and facilitate multi-stakeholder partnerships. Centre for Development Innovation Wageningen UR.

concern or aspiration while being driven by different interests and establish alliances to achieve a common practical purpose. The partnership structure aims at tackling drawbacks and enhancing strengths from an issue, bringing together the concerned actors, to work, learn, agree and build consensus on practice and policy changes toward sustainability. Among other activities, the networks can foster dialogue and learning, draw practical experience, produce scientific evidence, regulatory tools and good practices for incentivizing policy maker to prompt behaviour changes at local, national, regional and global level. One network example is the Global Agenda for Sustainable Livestock (GASL), which addresses simultaneously the environmental, health, social and economic impacts from livestock sustainability issues, including AMR.

I.II Research problem

Risks from AMR are several and with different aetiologies spanning in a variety of policy domains if we consider the whole system production chain of livestock food products. At the farm level AMR can be prompted to humans (mainly farmers and veterinarians) via direct contact with resistant animals exposed to AMR because of over prescription practices and below standard infection controls from animal health professionals. At this stage, the humans can be exposed also through indirect channels, such as manure with residues that contaminate the farm environment (water, crops, etc.). At the slaughtering and processing stages, direct contact with infected carcasses can foster the resistance to antimicrobials for employees, and ultimately at the consumer level, direct ingestion of products with residues of animals previously exposed to the drug and medicated feed for prophylactic purposes and, in some countries, for growth promotion can cause AMR.
In addition, several vectors allow resistant bacterial plasmids and clones to be transported between different environments and geographical regions, such as human beings' movements, insects, animals, agricultural practices and unmonitored waste (pharmaceutical manufacturers, hospitals, and livestock producers) that contaminates waters. In addition, AMR can spread also "horizontally", because agents can transfer resistance genes to other microbes, including across microbe species. In the range of risk cause from AMR, other factors such as governance, corruption and public spending on health programmes seem to play an indirect role in the contribution of the prevalence.
In considering these risks it also worth it to consider that, beside all these interconnected and multi-domain risks associated to the over administration of drugs, antibiotics are still essential to cure and preserve animal health and welfare. Measures to contain the development of AMR or its transfer if not carefully considered can result in the risk to develop much more dangerous public health risks, fostering the origin for example of more aggressive in terms of mortality and morbidity pathogens.

Provisions for this public good are generally the responsibility of public authorities: national governments and the multilateral institutions. Such variegated, interconnected and multi-domain

issues that find place in different policy areas end up being unavoidably addressed in different subareas of law – encompassing veterinary good practices, veterinary products, animal feed, farmers good practice with waste, manure and water management, animal welfare, official controls, human diet and promotion of protein transaction and drinking water contamination to cite a few. These are typically regulated in different legal instruments and areas of law, such as food safety, feed safety and environmental law, which make it highly complex to have a holistic view and best approach to the AMR issue as a whole. Additionally, the regulation for AMR risks becomes consequently very fragmented at the official governmental level and therefore questionable in its effectiveness, because all the different regulations have different requirements for risk assessment and conduct.
What is more, also in international trade under WTO law the different subareas of law in terms of public good governance are governed by different Agreements.
A public good such as AMR as highlighted above requires collective actions through multistakeholder political processes, next to the legal subsystems that work as regulatory authority to effectively integrate and assemble all evidence brought from each partner might indeed be more effective for an issue that requires a holistic approach.

I.III Aim and research question

The aim of this thesis is to analyse in the context of WTO disciplines the three AMR governance possibilities and respective regulatory approaches emerged from the literature. The study will begin with an overview of international recognized standards, EU unilateral measures and multi-stakeholder networks tools to provide a better understanding of the different regulatory approaches. The three methods are then going to be evaluated with the objective to understand which trade law measures and main provisions could apply in each case. Consequently, based on the understanding of the research a tentative assessment of the most effective approach in terms of compliance with trade law and resolution of AMR in all its risks will be drawn.

The following research question and related sub questions will be addressed:

What would be the ideal governance mechanism for the control of AMR in globally integrated food chains?

To answer this question, the following sub-questions are relevant:

- What are the regulatory risks linked to AMR?
- What are the regulatory approaches with respect to AMR and food production risks that emerge from each proposed governance model?

- Which WTO measures are applicable for the three regulatory options? SPS, TBT, GATT?
- Are there any incongruence between the regulatory approaches and the cited agreements that could undermine trade and public health?
- Is there a regulatory approach that could be more effective than the others to tackle AMR in food production in all its risks (sustainably)?

I.IV Thesis Statement

To what extent the three governance approaches and respective regulatory instruments, in the context of several WTO Agreements (such as the GATT, SPS and TBT Agreements) are effective to regulate AMR risks safeguarding economic interests and at the same time the global health? In other terms, do new innovative multisectorial and disciplinary network of stakeholders that pursue a same final goal can prevail in respect to classic governance mechanisms models such as the multilateral and unilateral ones to safeguard both economic and health interests?

I.V Significance of the study

AMR is a complex phenomenon to govern that however requires a fast action. Global governance is struggling to find ways to deal rapidly with the regulation of AMR risks under current international standards. And national measures are not perceived as being optimal to regulate the issues at the global level without threatening the smooth transaction of international trade in food products. Multistakeholder partnerships are emerging as a third governance option securing support to raising awareness and trying to develop fit-holistic solution in line with sustainable development.
Since AMR seems to be increasingly related to trade transactions of food products among countries, this study is adding to the debate of AMR governance the analysis of the trade factor of the issue. AMR governance mechanisms and respective risks regulation instruments are going to be looked through the lenses of WTO law, with the attempt to offer a novel approach to the establishment of the ideal governance mechanism for highly complicated public good issues.

I.VI Methodology

This thesis adopts a doctrinal research method, which encompasses a legal and critic examination of all the current legal sources on the topic of AMR in the food chain. This method is concerned with legal prepositions and doctrines that allow the researcher to look into the law, including all legislation, case law and rules, with the aim to find concepts and principles to reveal law statements relevant to the topic under investigation. The final objective is to establish "an arguably correct and complete

statement of the law on the matter in hand"[95]. One big limit of the doctrinal method is that it does not question the application of the law, but rather just limits itself to specific facts on the legal texts and researching into the law, which is problematic particularly in those possible- evolving areas such as scientific knowledge. The type of research being restricted to the analysis of the textual law with only reference to case law and doctrine has been criticized for being little interdisciplinary[96]. The author of the thesis has tried to overcome this limitation applying her degree on veterinary medicine on the topic under investigation.

The present thesis begins with assembling scientific facts on AMR and grasp those relevant to the law in order to identify specific legal issues connected to the area of study and formulate the research questions (I). Subsequently an overview and analysis of three governance models emerged from the literature (multilateral, unilateral and multistakeholder mechanisms) together with the respective relevant regulatory instruments and frameworks on AMR, is going to be conducted to demonstrate the present legal landscape on the area of study (II). The thesis continues further to examine the relevant WTO disciplines that apply to every regulatory instrument. Finally, the thesis discusses the provisions of the applicable disciples on the problem of the study by referring to concerned case laws, law on interpretation in international and WTO law, notably Articles 31, 32 and 33 of the Vienna Convention on the Law of Treaties, that the Appellate Body recognized as the approach that could be exercised in interpreting WTO laws[97] and legal theory (books, commentaries, law review articles, newspaper article and internet documents) (III). Conclusions and tentative solutions for contributing to the legal issue are drawn in the final part of the thesis (IV).

I.VII Limitations to the Study

Only three typologies of governance approaches and relative regulatory frameworks are discussed in the context of this thesis, although other approaches such as private standards and NGOs standards alone may also be relevant. In addition, the author's mastery legal methods are not comparable to that of a trained lawyer with a law degree. A limitation on this research is the very little literature on a legal analysis of antimicrobial resistance risk regulation within WTO disinclines. Additionally, while AMR risks have been addressed to certain extent, current and described legislative instruments are in phase of amendments, the scientific data is much contested and the political debate is very sensitive, therefore information is likely to arise and change in the near future.

[95] HUTCHINSON, T. 2017. Doctrinal research: Researching the jury. In: WATKINS, D. & BURTON, M. (eds.) Research methods in law. Routledge, 7-33.
[96] Gawas, V. M. (2017). Doctrinal legal research method a guiding principle in reforming the law and legal system towards the research development.
[97] Van Damme, I. (2009). Treaty interpretation by the WTO Appellate Body. Oxford University Press on Demand.

PART II AMR GOVERNANCE MODELS AND REGULATORY APPROACHES

To globally regulate antibiotics and AMU, law operates upon different levels of jurisdiction, which includes the public and private domains: both international and national legal instruments could be effective, however resolutions that are voluntary could also be important, especially to promote the multisectorial collaboration over a multifaceted issue[98]. To understand the ways in which the law can help to address the collective nature of AMR, it is important to recognize the different models of global regulatory governance that are available. These can be categorized in three types of standard-setting activities: multilateral and unilateral regulations, at the traditional public level, and soft and voluntary standards set by private entities or multistakeholder partnerships and networks. International law at the multilateral level extends beyond national borders and applies worldwide in those Member countries that have accepted its obligations, domestic laws apply within traditional state-centred systems and do not extend beyond the jurisdiction and borders of countries and multistakeholder standards are voluntary measures under non-state governance systems.

In relation to these notions, this section illustrates the main governance models for the regulation of AMR and its risks emerged from the literature. These three methods include:
multilateral efforts and cooperation for the stipulation of harmonized international standards from international organizations such as the Codex Alimentarius Commission (Codex), and the International Office of Epizootics (OIE) that work as a reference for the WTO law under the SPS Agreement [99];
domestic unilateral approaches with the example of the new EU approach to AMU at animal husbandry level; and transnational multi-stakeholder governance and voluntary private- like standards.

II.I Cooperation on AMR at the multilateral level: OIE, FAO and WHO

Infectious diseases know no borders and when an animal (or its product) leaves one continent and lands in another one because of trade, if infected with a microorganism, it could bring a new inflection in a geographical region that is not endemic for that disease[100]. This can potentially generate irreversible impacts for farmers and producers as well as for public health, such as in the case of zoonotic diseases and AMR. The need for strong international cooperation on good global and multilateral governance to control animal diseases as well as effective integration of food safety to better control foodborne zoonoses and safeguard international trade, national economic interests, as

[98] Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.
[99] Gruszczynski, L. (2010). Regulating health and environmental risks under WTO law: a critical analysis of the SPS agreement. OUP Oxford. Chapter 3 P. 76
[100] OIE (2020). Intenrational standards. Retrieved from https://www.oie.int/en/for-the-media/amr/oie-amr-standards/ (avvessed on August 26, 2020)

well as the global health is therefore of outmost importance[101]. However although the WHO announced AMR as one of the major threat to humans of the last 100 years, at global level only a small number of international organisations (FAO, OIE, WHO) are dedicated to tackle the problem of AMR as part of their mandate, and within these multilateral organisations progress has shown to be quite slow because of major disagreements on objective, difficult prioritisation and lack of government engagement[102]. In addition, the COVID-19 pandemic has led to underfinancing of the WHO, and thus more dependency for funding on pharmaceutical companies will be needed (which are antibiotic providers).

In terms of risk regulation, under the WTO, the Members have the right to take SPS measures "necessary for the protection of human, animal or plant life or health", provided that these are not inconsistent with the Agreement's provisions. The Agreement was designed to strike balance between [103]liberalisation of trade in agricultural food products and governments' will to tackle legitimate agricultural policy goals, including for instance the regulation of trade of live animals and raw plants, processed food and the final products that reach consumers' table. The SPS framework ensures as a by-product of trade liberalization food safety by encouraging countries legislative harmonisation through international standards[104], as well as encouraging members to reconsider the negative consequences of disproportionate unilateral measures[105][106]. However, the SPS discipline also safeguards the sovereign of Member countries to take necessary actions to protect human, animal or plant life if sustained by scientific reasons and evidence[107].
Under the SPS Agreement international standards possess a quasi-legislative authority and serve as a reference and advisory role for policy makers and regulators at the national level to put in place control systems in order to provide safe food and protect consumers' health. Although there is no obligation for governments to accept the texts, as in nature they are not binding, despite their advisory nature, the adjudication of major international trade conflicts turns in part upon them, as recognized benchmark for food safety[108]. Thus, countries are generally encouraged to comply with the SPS disciplines or base their rules upon the standards.

[101] Hathaway, S. C. (2013). Food control from farm to fork: implementing the standards of Codex and the OIE. Rev Sci Tech Oie, 32, 479-485.
[102] UCL (2019). The Need for Global Governance of Antimicrobial Resistance retieved from https://www.ucl.ac.uk/global-governance/news/2019/jan/need-global-governance-antimicrobial-resistance (accessed August, 26 2020).
[103] The Agreement on Sanitary and Phitosanitary measures. Article 2
[104] Amtenbrink, F., Prévost, D., & Wessel, R. A. (Eds.). (2018). Netherlands Yearbook of International Law 2017: Shifting Forms and Levels of Cooperation in International Economic Law: Structural Developments in Trade, Investment and Financial Regulation (Vol. 48). Springer. Chapter 8 p 238
[105] Ibidem
[106] Baral, P., Danik, M. E., & Hoffman, S. J. (2019). Leçons tirées de dix pays sur la réglementation des antimicrobiens pour les animaux d'élevage. Canadian Journal of Law & Society/La Revue Canadienne Droit et Société, 34(3), 521-553.
[107] Amtenbrink, F., Prévost, D., & Wessel, R. A. (Eds.). (2018). Netherlands Yearbook of International Law 2017: Shifting Forms and Levels of Cooperation in International Economic Law: Structural Developments in Trade, Investment and Financial Regulation (Vol. 48). Springer. Chapter 8
[108] Stewart, T. P., & Johanson, D. S. (1998). The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics. Syracuse J. Int'l L. & Com., 26, 27.

Three relevant multilateral organization are recognized by the world's food and agricultural communities for the coordination of information and standard setting concerning zoonoses, animal infectious diseases and food safety issues under the SPS Agreement:
Codex Alimentarius (CAC) for food safety, the International Plant Protection Convention for plant health, and the OIE for animal welfare, health and animal disease transmittable to humans[109] [110]. More in specific, in the context of food safety and animal health, the OIE has the responsibility for developing standards that could help Member countries monitoring, detecting and controlling diseases and zoonoses that can affect food, while the CAC has the mandate to develop standards related to food safety as such[111]. Because of the interconnection of animal health and food safety, which is the area of the CAC under the SPS Agreement, the mandates of the two organizations often present strong overlapping areas. To avoid the possible duplication of efforts and gaps, the two bodies have established a cohesive cooperation to develop guidance for foodborne zoonoses taking into account as a reference framework the farm to fork approach[112] [113].

Through international and global collaboration, the OIE and Codex contribute to optimal animal health, which is essential for safe food contributing to the elimination of hunger, ensure quality of life for farmers and economic income, and finally contribute to the resilience of the environment[114]. Serving as a basis for national legislations of Members' countries, the international standards developed by the two bodies contribute to sustainable development and the attainment of the Sustainable Development Goals (SDGs). They are of particular importance for LMICs because not sufficiently legally developed to provide strong regulatory frameworks for AMU and best practices to avoid the several impacts of AMR. As such, the philosophy of the organizations is that only by mobilising all countries to proactively collaborate on the AMR issue and to implement measures for the responsible and prudent use of the drugs, it will be possible to halt the spread of the problem globally.

The Agreement does not make any legal distinction between standard, guidelines, or recommendation, though in terms of context, residue standards are more precise and asks for more specific requirements for countries (such as specific numeric values, limits and units) [115]. For the sake of simplicity in this thesis considers the term "standard" to address the whole range of legal texts defined

[109] The Agreement on Sanitary and Phitosanitary measures. Article 3
[110] The Agreement on Sanitary and Phitosanitary measures. Annex A
[111] Slorach, S. A. (2006). Assuring food safety: the complementary tasks and standards of the World Organisation for Animal Health and the Codex Alimentarius Commission. OIE Scientific and Technical Review, 25, 813-21.
[112] Ibidem
[113] Hathaway, S. C. (2013). Food control from farm to fork: implementing the standards of Codex and the OIE. Rev Sci Tech Oie, 32, 479-485.
[114] OIE (2020). OIE international Standards to control antimicrobial resistance. Retrieved from https://www.oie.int/en/for-the-media/amr/oie-amr-standards/
(accessed August 26, 2020)
[115] Gruszczynski, L. (2010). Regulating health and environmental risks under WTO law: a critical analysis of the SPS agreement. OUP Oxford. Chapter 3 P. 89

by the Agreement. Some of the most important standards available on AMR regulation at international level are going to be outlines in the next session.

II.I.i OIE standards in the Terrestrial Animal Health Code

Specialist Commissions and Working Groups bring together international experts within the network of the OIE Collaborating Centres and Reference Laboratories to prepare and set OIE standards. International Committee composed by the members OIE delegates nominated by the governments later adopts the texts. The standards are continuously updated to keep pace with scientific development and each year a revision is performed by the OIE Assemble Delegates[116].

The OIE has adopted a number of guidelines on AMR that Member countries can use, included in the Terrestrial Code[117], the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[118] (Terrestrial Manual) and the Aquatic Animal Health Code (Aquatic Code)[119]. These are internationally recognised standards and used to harmonise frameworks across countries for managing veterinary medicinal products and for AMR surveillance and monitoring programmes at country level. They are essential for the development of the risk analysis and for risk management measures and tailored to each country's geographical and socio-political realities and variables. The main characteristics of these standards are going to be outlined in this section.

Guidelines on surveillance and monitoring

Surveillance of AMR found in animal, its food or the environment in which they are raised is a critical part for a programme that seeks to limit and reduce the spread of AMR. Surveillance is also a key step for antimicrobial prescribers to optimize the choice of a treatment for a certain animal health condition over another[120]. The OIE guidelines on the harmonisation of national AMR monitoring and surveillance programmes in animal and ASF are laid down in chapter 6.7 of the OIE Terrestrial Code[121]. The main objective of the text is to set criteria for countries to implement the surveillance programmes over time in a harmonised way in order to analyse trends, detect emergencies, provide data for the risk analysis to public health and respond appropriately in relation to the reported threats. When defining a sampling strategy, the guidelines recommend taking into account sample sources (food, animal, feed), the bacteria to be monitored, the class of antimicrobial and the type of

[116] Slorach, S. A. (2006). Assuring food safety: the complementary tasks and standards of the World Organisation for Animal Health and the Codex Alimentarius Commission. OIE Scientific and Technical Review, 25, 813-21.
[117] OIE (2017). Terrestrial Animal Health Code
[118] OIE (2017). Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
[119] OIE (2017). Terrestrial Animal Health Code. Aquatic Animals Health Code
[120] Orand, J. P. (2012). Antimicrobial resistance and the standards of the World Organisation for Animal Health. Revue Scientifique et Technique-OIE, 31(1), 335.
[121] Ibidem

data to be recorded. Chapter 1.1.6 of the Terrestrial Code sets guidelines that enable laboratories methodologies for bacterial antimicrobial susceptibility testing. The guidelines stress on the importance that every laboratory should use similar procedures as well as harmonised standards for the interpretation of the outcomes, thereby allowing the comparison between different geographical regions This reflects the provision set in Article 5.2 of the SPS, which specifies that in the assessment of risks, WTO Members shall take into account relevant inspection, sampling and testing methods[122]. Chapter 6.8 of the Terrestrial Code defines the approach to be implemented for the collection of quantitative information to evaluate antimicrobial exposure patterns in antimicrobial use depending on the species and class of drug at stake. This information can be useful for the interpretation of surveillance data; evaluation of measures and implementation of more targeted and tailored mitigation strategies when required.

Guidelines on legislation, use of veterinary medicinal products and risk analysis

The OIE adopted guidelines laying down recommendations for developing legal frameworks at the national level[123]. These guidelines are important to enable and guide Members to develop and set effective policies protecting animal health and economic revenues, enhance with legal power national Veterinary Services and functions on AMR surveillance, rapid response, prevention and control of animal infectious diseases. In addition, the guidelines propose specific rules for each technical sector in relation to antimicrobials. For instance, a chapter[124]of the guidelines is dedicated to the regulation of the veterinary medical products throughout the whole production chain, including marketing authorisation and advertising of the drugs, raw materials use, manufacturing of the product together with its distribution and optimal quality.

Chapter 6.9[125] of the Terrestrial Code sets recommendation for all stakeholders to ensure the prudent use of the drugs including competent authorities, which should establish the regulatory framework for antibiotics, the pharmaceutical industry, the retailers, the veterinarians and the food producers. The chapter put emphasis that careful attention should be ensured at all stage of the process of the life cycle of an antibiotic, including authorisation, administration and waste management steps. Lastly, chapter 6.20[126] of the Terrestrial Code lays down the methodologies for Members to develop a risk analysis for AMR and manage the risk for both animal and human health from AMU in animals. The steps include hazard identification from surveillance programmes, the risk assessment of the resistance, the exposure assessment to the hazard previously identified and a potential consequence

[122] The Agreement on Sanitary and Phitosanitary measures. Article 5
[123] OIE (2011). Guidelines on veterinary legislation.
[124] Ibidem
[125] OIE (2017). Terrestrial Animal Health Code. Chapter 6.9
[126] Ibidem

assessment for being exposed to the hazard. These steps are essential for subsequently ensuring the risk management options and risk communication among the key actors of the sector appropriately.

II.I.ii Codex Alimentarius standards

Codex standards are based on the principle of sound scientific analysis and evidence, and the CAC has been working on AMR mainly through the activities of the Committee on Residues of Veterinary Drugs in Foods and the ad hoc Intergovernmental Task Force on Antimicrobial Resistance. The standards gather the inputs of experts from the WHO and FAO (Joint FAO/WHO Expert Committee) and from ad hoc expert consultations. The development of the standards is a very lengthy process and includes submitting a draft text to governments and international organizations, including the OIE, for comments[127].

Principal texts developed by Codex on AMR are the 'Code of Practice to Minimize and Contain Antimicrobial Resistance' (CAC/RCP 61-2005[128][129]) and 'Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance' (CAC/GL 77-2011[130]). AMR is also addressed in other texts: the 'Code of Practice on Good Animal Feeding' (CAC/RCP 54-2004[131]), the 'Code of Hygienic Practice for Eggs and Egg Products' (CAC/RCP 15-1979[132]) and the 'Code of Practice for Fish and Fishery Products' (CAC/RCP 52-2003[133]).

Also antimicrobial resistance marker genes in recombinant-DNA plants and recombinant-DNA microorganisms; non-genetically modified microorganisms (for example, starter cultures), which are intentionally added to food for a technological purpose; and certain food ingredients which could potentially carry AMR genes, such as probiotics issues are covered in other existing Codex and/or internationally recognised guidelines.

The main standards are going to be outlined in this section.

Code of practice to minimize and contain antimicrobial resistance

The document provides guidance for the responsible use of antimicrobials in food producing animals and for the professionals of the sector. The objective of the document is to minimize the development of AMR and the risks to public health. In particular, the text addresses exclusively the use of antimicrobials at veterinary medicine level in livestock use for food purposes, and, although it

[127] Slorach, S. A. (2006). Assuring food safety: the complementary tasks and standards of the World Organisation for Animal Health and the Codex Alimentarius Commission. OIE Scientific and Technical Review, 25, 813-21.
[128] CAC (2005). Code of practice to minimize and contain antimicrobial resistance. *CAC/RCP*, 61-2005.
[129] Currently under revision
[130] CAC (2011). Guidelines for risk analysis of foodborne antimicrobial resistance. *Geneva: Food and Agriculture Organization*.
[131] CAC (2004). Code of practice on good animal feeding. *CAC/RCP*, 54-2004.
[132] CAC (1979). Code of hygiene practice for eggs and egg products (CAC. RCP).
[133] CAC (2012). Code of practice for fish and fishery products. *Code of practice for fish and fishery products.*,

recognizes the ecological role in the spreading of AMR, the code does not address the environmental sphere of the issue[134]. According to the text, veterinarians should control AMU, and in particular, AMU should be allowed only when its purpose is based on the results of surveillance and monitoring programs run by health professionals. The standards also define and describe the responsibilities of all the actors involved in the production and use of the drugs, meaning authorization, production, sale, supply, prescription and use in food-producing animals' steps. These steps involve in order: national regulatory authorities, the pharmaceutical industry, veterinarians, distributors and producers.

The national regulatory authorities must promote the constant quality and efficacy of veterinary antimicrobials ensuring that the illegal use of the drugs is not taking place. For instance, by making sure that health professionals only prescribe and use antibiotics when needed to treat animal pathologies. Furthermore, the text lays down that national regulatory authorities should coordinate with animal and public health professionals to promote the prudent use of antimicrobial and develop a structured approach to the investigation and reporting of the incidence and prevalence of AMR. The pharmaceutical industry should provide national authorities with all the information needed to establish the quality, safety and efficacy of the drugs and should market and advertise, in accordance with national legislation, only official authorized veterinary antimicrobials. Veterinarians should cover a key role in identifying properly diseases and pathologies and developing alternative prevention programs or treatments for infectious disease, including for instance changes in husbandry conditions and vaccination programmes. They should additionally ensure that the drugs are used only when necessary and in appropriate occasions. Emphasis is also put on the importance of keeping records on information use. Lastly, distributors of food-producing animals should use antimicrobial drugs only with the prescription of a veterinarian or health professional, keep records of supplies and encourage compliance with national guidelines. Producers should safeguard animal health and welfare and ensure that veterinary antimicrobials are used only when necessary and in accordance with the legal approved use.

Guidelines for risk analysis of foodborne AMR

The objective of these documents is to provide a science-based framework on the methodology for the analysis of AMR risks to human health associated to ASF, including aquaculture and feed. The guidelines set the requirements of risk analysis of foodborne AMR in sequence: preliminary risk assessment, risk assessment and risk management possibilities. Risk communication and surveillance are also addressed, but as integral part of the entire risk analysis process. The general principles set in

[134] Bruno, A. V., & Mackay, C. (2012). Antimicrobial resistance and the activities of the Codex Alimentarius Commission. Revue scientifique et technique (International Office of Epizootics), 31(1), 317-323.

the guidelines define the purpose of the risk analysis and the factors to be considered for risk assessment/risk management activities, as conferred in Article 5.2 of the SPS Agreement[135]. Such analysis should take into account the susceptibility of a microorganism to an antimicrobial drug, together with the possible consequences of human exposure to these resistant microorganisms.

Risk analysis requires focusing on the food commodity, the resistant microorganism, the determinants of the issue and the antimicrobial at stake. Monitoring and surveillance programmes of AMU's importance are also highlighted together with the need, where appropriate, to evaluate animal health aspects relevant to food safety. The preliminary risk assessment phase determines the scope and size of the food safety issue and, where necessary, the management and policy options. Important is the development of a foodborne antimicrobial risk profile with a description of the state of knowledge on the issue, the control measures and the possible management options. The Appendix to the Guidelines lists the main elements of a foodborne antimicrobial resistance risk profile. The risk assessment activities identify and assess the events that affect the frequency and numbers of AMR pathogens from which human health may be hampered through food and describe their magnitude and severity.

The four components of the risk assessment process are described in the guidelines:
Hazard identification (the foodborne AMR hazard of concern); exposure assessment, (estimation of the level of exposure to the hazard); hazard characterisation (the characteristics of the hazard, the food and the host, to determine the probability of disease after exposure); risk characterisation (findings from the previous steps to estimate the actual risk). The risk management includes regulatory and non-regulatory measures to tackle the issue based on the risk assessment. The section further stresses the importance of evaluating, monitoring and reviewing the measures. The guidelines also emphasise that good veterinary and good hygienic practices should be in place from the 'farm to fork' steps. Risk communication should help to ensure a common perception of risks and risk management solution among all the parties involved: risk manager, assessors, consumers and industry.

"Code of Practice on Good Animal Feeding" (CAC/RCP 54-2004), "Code of Hygienic Practice for Eggs and Egg Products" (CAC/RCP 15-1979) and "Code of Practice for Fish and Fishery Products" (CAC/RCP 54-2004)

"Code of Practice on Good Animal Feeding" lays down the definition of medicated feed and lists for the feed additives and veterinary drugs to be assessed for safety and use, as preapproved by the competent authorities. "Code of Hygienic Practice for Eggs and Egg Products" considers that good husbandry practices should be essential to reduce the likelihood of pathogens and the risks to human

[135] The Agreement on Sanitary and Phitosanitary measures. Article 5

health, and that the use of veterinary drugs should always be appropriate to the situation at stake. Lastly, the "Code of Practice for Fish and Fishery Products" recognises that resistance may be promoted by uncontrolled practices and use of medicinal products in the treated fish and in the environment. It further highlights the responsibility of the veterinarians and professionals for the prevention of AMR and for the importance of the implementation of sound management and good animal husbandry in reducing the likelihood of fish diseases. Emphasis is also put on the fact that drugs must be used only when needed and with the right disease.

Codex new activities

Codex and the Codex Task Force on Antimicrobial Resistance (TFAMR) food standards programme ad hoc codex intergovernmental task force on AMR are currently developing two new key documents that will be the basis for new and renewed international standards applied to foodborne AMR:
A revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005[136]) and a revision of the Guidelines on Integrated Surveillance of Antimicrobial Resistance[137].
The mandate of these new texts will be to address the entire food producing chain and to endorse directly and indirectly antibiotics in the food chain, with guidance especially on the highly contested political topic of which class of antibiotics will be permitted at animal husbandry level and under which circumstances[138].

Indicating a broader scope of elements to be considered for risk assessment, surveillance and scientific advice on AMR, the documents aim at filling gaps of current international standards. The texts are being designed in line with the One Health philosophy considering the whole food chain and the production environment, previewing a closer collaboration with human health, animal health, plant health, environmental specialists' relevant authorities in order to protect the global health[139].
In addition, the texts are indented to help Members countries to cover the design and implement integrated policy frameworks and programs for the monitoring and surveillance system for foodborne AMR and AMU in animals, crops, as well as the environment (soils where crops are grown, irrigation water, manure, waste and packaging). These guidelines will be of importance, because there are currently important gaps on information on volume and use made of antimicrobials in animals and a very little number of countries systematically test food imports for the presence of AMR

[136] CAC (2018). Proposed Draft Revision Of The Code Of Practice To Minimize And Contain Foodborne Antimicrobial Resistance (CXC 61-2005) retrieved from http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-06%252FWD%252Famr06_05e.pdf (accessed August 26,2020)
[137] CAC (2018). Proposed Draft Guidelines On Integrated Monitoring And Surveillance Of Foodborne Antimicrobial Resistance retrieved from http://www.fao.org/faowhocodexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-06%252FWD%252Famr06_06e.pdf (accessed August 26,2020)
[138] George, A. (2019). Antimicrobial Resistance (AMR) in the food chain: trade, one health and codex. Tropical medicine and infectious disease, 4(1), 54.
[139] Ibidem

microorganisms[140].

TFAMR negotiations are currently being held and the open-source working draft texts indicate the complexity and political sensitivity of these negotiations[141]: comments to the document stresses that for instance the surveillance and monitor programmes must be performed in a stepwise approach that would take into account the capacity and priorities of the Member countries. Some of the complex issues yet to be dealt include establishing the scope of the "food chain", securing antimicrobials of importance for human medicine and the interpretation attached to evidence versus precautionary principle[142].

Issues with global multilateral governance

Although some international organizations are active in terms of AMR of regulations, a failure of the multilateral system is evident. There is generally a marked absence of political commitments on an international scale given the ever-growing trends of AMR touching upon every part of the world and progress is moving rather slow while the issue would require a fast action. In addition, the COVID-19 pandemic has highlighted the inability of international structures to offer an adequate and swift response to such major global health issues, where AMR, although without clear symptoms, is more serious than COVID-19[143].

It has been noted that the one of the main failure at the international level is that the few active organisations (The tripartite: FAO,OIE, WHO) tend to find technical solutions separately in their respective sectors of expertise - human and animal health, environment, aquaculture, trade, food and farming- to solve a same goal, leading to a globally fragmented strategy with disintegrated policies and regulations which are hard to follow for singular countries[144]. As such, the international standards on AMR briefly outlined in the previous section mainly deal with the animal health and veterinary sector, while there is an emerging consensus that efforts should focus on different objectives and sectors: correct AMU (both human and animal health), eliminating antibiotics for growth promotion in food production, improve prevention , water, sanitation, and hygiene in all sectors[145]. Some of these thematic are neither part of the SPS Agreement, nor even the TBT.

In addition global public good need cooperation, while financing and political will at the national level is tremendously lacking and these organisations have little authority to oblige countries complying with multilateral regulations, apart under the SPS Agreement where international standards set by the

[140] Ibidem
[141] Ibidem
[142] Ibidem
[143] UCL (2019). The Need for Global Governance of Antimicrobial Resistance retrieved from https://www.ucl.ac.uk/global-governance/news/2019/jan/need-global-governance-antimicrobial-resistance (accessed August 26 2020).
[144] Ibidem
[145] WHO (2018). Antimicrobial resistance. Retrieved from www.who.int/mediacentre/factsheets/fs194/en/ (accessed Sept 8, 2020)

Codex and OIE are a benchmark for SPS measures as will be seen later in the thesis [146]. The nowadays-globalized world by the economy and technology is divided into many countries that adopt different measures with scarce coordination and effectiveness for global issues, which can cause dire consequences for world economy and the society as a whole and costs thousand. A public good problem such as AMR with multidimensional challenges (social, economic, environmental dimensions) would require effective cooperation and coordination to build innovative and muldisciplinary approaches in order to adequately tackle a strong interdependence between several policy issues through the SDGs.

Current multilateral systems are lacking effective mandates to ensure national commitment through binding instruments, and a process for commitments reporting. Funding to ensure innovation and alternatives to antimicrobials are also missing and ultimately multilateral institutions lack the ability to mobilise stakeholders outside the public domain[147]. Thus, a much-needed reform of multilateral institution has been called by many already.

II.II Approach on AMR at the unilateral level: the European Union

Trade is very important for the economic prosperity of single countries and liberalization of international trade has been increasingly supported over the years. At the same time, however it has been noted that the public debate on globalization and interrelated value chains among countries shows that the opinion of citizens and policy makers has now changed, especially in regards of sensible topics such as public health and food safety in relation to modern and large-scale intensive agribusiness systems[148]. Increasing concerns on zoonotic infectious diseases and AMR based on different social aspirations and fears of pandemic potentials are in fact nowadays very common[149]. In addition to that, in the domain of AMR, international collaboration has showed to move rather slowly because of different interests and level of commitment leading lead a number of state-centred authorities to turn towards a wide-range of national, or unilateral, measures[150] [151]. This is in order to safeguard more effectively the citizens' health and consumers' interests within the own jurisdiction, and possibly overcome the incomplete substantively and procedurally measures at the multilateral level.

[146] Global democracy (2020). Coronavirus For A Global Democratic Governance retrieved from https://globaldemocracy.wixsite.com/covid19?lang=en (accessed Sept 8, 2020)
[147] Rochford, C., Sridhar, D., Woods, N., Saleh, Z., Hartenstein, L., Ahlawat, H., ... & Cassels, A. (2018). Global governance of antimicrobial resistance. The Lancet, 391(10134), 1976-1978.
[148] van den Bossche, P., Schrijver, N., & Faber, G. (2007). Unilateral Measures Adressing Non-Trade Concerns. Peter Van den Bossche, Nico Schrijver, Gerrit Faber, UNILATERAL MEASURES, The Ministry of Foreign Affairs of The Netherlands. Pp. XXIX - XXX
[149] The Guardian (2020). Is factory farming to blame for coronavirus? Retrieved from https://www.theguardian.com/world/2020/mar/28/is-factory-farming-to-blame-for-coronavirus (accessed August 26, 2020)
[150] Pattberg, P., & Widerberg, O. (2016). Transnational multistakeholder partnerships for sustainable development: Conditions for success. Ambio, 45(1), 42-51.
[151] Ibidem

At the public level, where the authority and regulatory power come from the State, the EU especially has been a very active and progressive entity in support of the reduced AMU in food animal production. Already in 2001, the Union recognized the importance of the issue, and established a first policy instrument with the "Community Strategy against Antimicrobial Resistance[152]" to address surveillance, prevention and control, research and product development at Member States level. Four years later, it posed an EU-wide ban on the use of the antimicrobials as growth promoters[153] in animal feed in Regulation on additive for use in animal nutrition[154], provoking trade disputes at the international level. Subsequently in 2011, the Union reinforced its policy with the One Health holistic philosophy to better consider the interrelation of human, animal and the environment. As such, even though the Union has a limited mandate in human health policy[155], which is a national competence, Decision 1082/2013[156] defines AMR as serious cross-border threats to health and establishes that actions at Union level are needed to tackle the emerging issue. It has been in fact recognised that to face the regional and global AMR challenges, Member States alone cannot tackle the problem on their own and thus they are now required to monitor and report to the EU the presence of resistant zoonotic and commensal bacteria in food of animal origin.

With the integration of the One Health philosophy, the EU has been focusing a lot on the interconnected issues from AMR. In 2017 following WHO Global Action Plan guidance, which includes strategic objectives to optimise the use of antimicrobial medicines in human and animal health, a renewed EU strategy has been established with the modern "European One Health Action Plan against antimicrobial resistance"[157]. The new strategy is based on three fundamental pillars: making the EU a best practice and leader region, boosting research development and innovation and shaping the global agenda. The Action Plan supports Member States and promotes collaboration among sector and societies to share evidence, awareness in consumption, promote proper use of the drugs, prevention and control on AMR risks and boost research for alternative treatments. In addition, following this philosophy the Union has also worked on renewing its legislative frameworks regarding AMR. In 2018, it has agreed to update the legislations regarding VMPs and medical feed with the VMPs package considering the characteristics of the veterinary and animal health sector. The package, already in force, will be applied as per January 2022.

[152] EU (2001). Community Strategy against Antimicrobial Resistance.
[153] This ban was reinforced under the new EU Regulation on veterinary medicinal products.
[154] EU (2003). Regulation 1831/2003/EC on additives for use in animal nutrition, replacing Directive 70/524/EEC on additives in feeding-stuffs.
[155] Human health is a national competence. Articles 6 and 168 of the Treaty on the Functioning of the European Union (TFEU) give the Union competence to carry out actions to support, coordinate, supplement and encourage cooperation between Member States, for the protection and improvement of human health.
[156] EU (2013). Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC
[157] EC (2017). A European one health action plan against antimicrobial resistance (AMR). European Commission.

II.II. i VMPs package: Regulation EU 2019/4, 2019/5 and 2019/06

The main aim of the package, composed of three legislations, is to increase the availability of VMPs in the EU, improve the function of the EU market and strengthen innovation while providing measures to protect the public and animal health, and the environment, offering an important springboard for further progress in order to preserve the efficacy of existing and critical antimicrobials. Overall, the key objective of the EU with the new framework is to encourage, promote the responsible use of antimicrobials among professionals of the sector, and promote health to ensure adequate antimicrobials protection and conscious animal husbandry practices. For instance, farmers will not be allowed to implement the routine prophylactic use of the molecules as a precaution to safeguard animals from protracting infectious disease, rather they will have to adopt better husbandry practices to safeguard animal health status and reduce antimicrobials use.
Based on the principle of marketing authorisation in the EU, the framework also promotes the functioning of the EU internal market with measures to encourage innovation, including harmonised provisions for the manufacture, wholesale and advertising of veterinary medicinal products.

In specific the three main regulations are:

I. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.
II. Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.
III. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

In terms of trade relations with third countries, two of the aforementioned legislations are important: Regulation (EU) 2019/4 which main purpose is to ensure appropriate standards for product quality and security as well as to open up for better treatment opportunities for sick animals in the EU, and Regulation (EU) 2019/6, which main purpose is to make further medicinal products available in the EU to treatment and prevention of animal illnesses. Regulation (EU) 2019/5 has been established to

reflect that the centralised marketing authorisation for VMPs in the EU will be separated from the corresponding regarding human medicinal products, thus not having impacts on international trade relations.

More in concrete, the two important regulations for international trade encompass stringent and revisited measures, including:
Simplifying the procedures for marketing authorisation to new medicines, thereby reducing the administrative burden for companies of all size, and regulating a better use of antimicrobials in animals by further limiting their use in groups of healthy animals in routinely prophylaxis[158] procedures; preserving the effectiveness of critical antimicrobials by restricting certain metaphylactic[159] practices and giving the possibility, based on a risk assessment methodology, to Member States to reserve and ban from third countries the use of certain molecules destined for human medicine only; strengthening the ban on imports on the use of antibiotics for animal growth and yield increase purposes; improving the protection on AMR of the European consumers through imports of live animals and products of animal origin; strengthening pharmacovigilance and controls; and making it mandatory to perform an environmental risk assessment for the authorization process of new VMPs[160]. About medicated feed, feed business operators and manufactures are now required to comply with specific criteria and obligations before getting a marketing approval, as well as comply with more harmonised requirements to avoid cross contamination of feed with antimicrobial substances; additionally, a prescription from a professional is now mandatory to use medicated feed containing antimicrobials throughout the whole Union. Ultimately, the package sets also that medicated feed for prophylaxis purposes is prohibited[161].

The framework explicitly stipulates that controls on VMPs must be performed along the whole chain of distribution. Additionally, it stresses the importance that sources of ARM could potentially originate both from inside and outside the Union, resulting all operators from trading partners subject in "a non-discriminatory and proportional manner" to the EU obligations[162]. However, more detailed explanations about imports are expected in the near future from delegated acts of the European Commission [163]. The EU in the framework points out that its requirements will be compliant with

[158] "On a population basis, prevention is the administration of an antimicrobial to a group of animals, none of which have evidence of disease or infection, when transmission of existing undiagnosed infections, or the introduction of pathogens, is anticipated based on history, clinical judgement or epidemiological knowledge". AVMA definitions retireved from https://www.avma.org/resources-tools/avma-policies/avma-definitions-antimicrobial-use-treatment-control-and-prevention (accessed on August 26,2020)
[159] On a population basis, control is the use of antimicrobials to reduce the incidence of infectious disease in a group of animals that already has some individuals with evidence of infectious disease or evidence of infection. AVMA definitions retireved from https://www.avma.org/resources-tools/avma-policies/avma-definitions-antimicrobial-use-treatment-control-and-prevention (accessed on August 26,2020)
[160] EU (2018) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
[161] EU (2018). Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed repealing Council Directive 90/167/EEC
[162] Ibidem recital 49 and Article 106.6
[163] Ibidem recital 93

international agreements, SPS obligations and be sustained on scientific evidence[164]. With this new approach, the Union is positive that international concern on AMR will be fostered and more cooperation at the global level will follow.

II.II.ii Concerns with the unilateral measures: AMR and international trade

Countries have a variety of option to experiment and select the best option to address to some extent the AMR issue. These could be taken in the form of: string command and control measures (prohibitions, restrictions), and price based measures (custom duties, taxes or incentives); border measures (bans, restrictions, custom duties) and internal measures (regulations, taxes, subsidies); measures applicable to imports only (*de jure* discrimination) or to both imports and domestic products (*de facto* discrimination); measures concerning the characteristic of the product and measures concerning the process and production methods; and measures concerning product-related processes and production methods and measures concerning non-product-related processes and production methods[165]. At the domestic level, countries can intervene at each of the different stage of the value chain of AMU and production[166]. However, the wide range of options and flexibility that countries have available for such a complex collective goods problem generally can lead to mixed and patched results throughout the globe with scarce results[167]. For instance, in a study examining 10 different countries domestic law measures to address the same AMR challenge, it has been evidenced that none of the analyzed country followed the same approach to tackle the same issue. The author of the study claims that because of the many links that exist between the spheres of activities at the heart of the AMR problem, the global results and effectiveness of the regulatory changes inducted by singular unilateral measure can be very difficult to predict[168]. A clear example could be the case of the use of sub therapeutic doses of antibiotics in food-producing animals (which has been linked to antibiotic resistant infections in humans). Although the practice has been banned in Europe, the U.S. and other countries regulatory authorities have been slow to act[169], rendering the effectiveness of the actions taken by a single geographical area questionable at the global scale.

As a result, although domestic law can mitigate a number of practices related to AMR, unilateral measures seem also limited in capacity[170]. If taken the example of the EU, of the many risks arising from the overall problem of AMR, as listed in part I (page 17), only reduction of resistance from the

[164] Ibidem recital 40
[165] van den Bossche, P., Schrijver, N., & Faber, G. (2007). Unilateral Measures Adressing Non-Trade Concerns. Peter Van den Bossche, Nico Schrijver, Gerrit Faber, UNILATERAL MEASURES, The Ministry of Foreign Affairs of The Netherlands. Pp. XXIX - XXX
[166] Danik, M. E., Baral, P., & Hoffman, S. J. (2018). De la ferme à l'assiette mondiale: Dix approches à la réglementation des antimicrobiens chez les animaux d'élevage. In C. Régis, L. Khoury, & R. P. Kouri (Eds.), Health law at the frontier (pp. 121–172). Montreal, Canada: Éditions Yvon Blais.
[167] Ibidem
[168] Baral, P., Danik, M. E., & Hoffman, S. J. (2019). Leçons tirées de dix pays sur la réglementation des antimicrobiens pour les animaux d'élevage. Canadian Journal of Law & Society/La Revue Canadienne Droit et Société, 34(3), 521-553.
[169] Duckenfield, J. (2013). Antibiotic resistance due to modern agricultural practices: an ethical perspective. Journal of agricultural and environmental ethics, 26(2), 333-350.
[170] Ibidem note 20

consumption of animal sourced food seems to be tackled consistently with the package. Countries are also given the option to leave some antibiotics for human use only as a way to safeguard also human health, but it seems to be left on a voluntary basis for Member States in the framework.
Some of the other issues that are interrelated to such the problem of AMR, are in fact found elsewhere in EU law: animal health as a regulation per se in the "Animal Health law[171]". Animal welfare is tackled in the Council Directive 98/58/EC [172] lays down the minimum standards for the protection of all farmed animals, AMR as waste and residual water in Directive 2013/39/EU6[173], which requires the European Commission to propose a strategic approach to the pollution of water by pharmaceutical substances. AMR at human level is regulated at national level because the EU does not have legal power to regulate human health at union level. All these fragmented pieces of legislation with different rules, risk assessment and risk management options render very questionable the efficacy of unilateral measures, because the issue seem not to be tackled in consistent way throughout all its faced as for instance required by the One Health approach.

In addition, besides the scarce efficacy at the scientific core of AMR, at trade level, unilateral measures seem to find hurdles with international relations as well. Taking the example of the unilateral measures analyzed in this thesis, some WTO Member countries expressed concerns regarding the new actions taken by the EU on VMPs. As per the current stages of the framework, Members condemn that the legislation is neither based on a risk assessment because the scientific evidence on AMR from the food chain is still unclear, nor is in line with international guidelines and principles recognized by the SPS Agreement, especially under Article 3[174]. They point that it turns out as more trade restrictive than necessary. According to Argentina for instance, the new EU approach would prevent market access for products from third countries where antibiotics are subject to different authorization procedures. In addition, the United States and Canada add that because of the legislation, countries would be obliged to come less to own regional conditions on diseases prevalence and animal health husbandry practices in order to comply with EU production standards[175]. Australia stresses the importance of retaining access to antimicrobials to protect animal health because important for maintaining health and biosecurity measures and thus to avoid animal welfare repercussions: the country points out that with good welfare practices it has successfully reduced the AMU. In addition, it stresses that measures, which would restrict prophylactic measures in food animal, would produce tangible adverse effect for its exports. Thus, the country suggests to the EU to focus on favorable health status of animals,

[171] EU (2016). Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')
[172] EU (1998). Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes. Official Journal L, 221(08), 08.
[173]EU (2013). Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. Off. J. Eur. Union, 226, 1-17.
[174] Ad Hoc Codex Intergovernmental Task force on Antimicrobial Resistance (2019). Matters Arising from Other Relevant International Organizations (OECD, World Bank, World Customs Organization, WTO) pp. 812Retrieved from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-06%2FWD%2Famr06_04e.pdf. (accessed on August 26, 2020)
[175] Ibidem

extensive farming systems, border controls, effective security measure for the prevention of the spreading of infectious diseases and strong regulatory frameworks on the registration and AMU rather than on bans and limits to drugs use[176]. Furthermore, in a study, it has been noted that a framework that might be very successful in one country, may in turn be ineffective in another context because the local variables are different depending on the geographical location and different realities of a state (disease epidemiology, environmental facets, and production systems)[177].

Overall, even though the global agreement exist that AMR issue represents a lot of complexities and actions are certainly needed, unilateral effort alone would unnecessarily pose restriction to trade and even possibly undermine the current multilateral efforts (unless through unilateral measures a country coerces others into stepping own AMR legislation). Because for a good impact on AMR, the complex challenges require more coordinated and international scientific efforts to be solved[178].

II.III The multistakeholder partnerhsip governance

With root causes ranging in a variety of fields and interdependent factors, spanning from health, food safety and agriculture to environment, trade and socio-economic development AMR is a very complex issue to deal with[179]. As such, government's efforts alone or independent international organizations generally has shown not to be able to grapple consistently with the urgent issue because of a variety of causes, including to cite a few conflicting interests, interconnectedness across scales and uncertainties regarding the scientific evidence available[180] [181]. The Tripartite Collaboration on AMR is the current international focused governance comprising the WHO, FAO, OIE. However, there are limitations with this governance because global public goods such as antimicrobials will sustain in time only if all countries engage in cooperation[182]. An approach with actions taken from across diverse sectors and involving broad range of actors and disciplines and truly global response to reinforce the effort against AMR is therefore required[183] [184].

This can be taken in the forms of deliberate, decentralized and flexible multisectorial collaboration, generally referred to with the term of multistakeholder governance. A multistakeholder partnership is

[176] Ibidem
[177] Danik, M. E., Baral, P., & Hoffman, S. J. (2018). De la ferme à l'assiette mondiale: Dix approches à la réglementation des antimicrobiens chez les animaux d'élevage. In C. Régis, L. Khoury, & R. P. Kouri (Eds.), Health law at the frontier (pp. 121–172). Montreal, Canada: Éditions Yvon Blais.
[178] Ibidem
[179] Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.
[180] Rochford, C., Sridhar, D., Woods, N., Saleh, Z., Hartenstein, L., Ahlawat, H., ... & Cassels, A. (2018). Global governance of antimicrobial resistance. The Lancet, 391(10134), 1976-1978.
[181]Breeman, G., Dijkman, J., & Termeer, C. (2015). Enhancing food security through a multi-stakeholder process: the global agenda for sustainable livestock. *Food Security*, *7*(2), 425-435.
[182] Ibidem note 176

[183] Ibidem
[184] Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.

defined as " Any collaborative arrangement among stakeholders from two or more different spheres of society (public sector, private sector and/or civil society), pooling their resources together, sharing risks and responsibilities in order to solve a common issue, to handle a conflict, to elaborate a shared vision, to realize a common objective, to manage a common resource and/or to ensure the protection, production or delivery of an outcome of collective and/or public interest[185]."
This governance activity generally takes place in and interactional way between countries as well as beyond national boundaries. Since these networks can take place within a variety of ways and encompass a range of different actors, they vary depending on each situation: some are known as public private partnerships for development, some other cross-sector collaboration, or even transnational network[186]. In the literature, there is not a broadly agreed definition of the term, but most scholars agreed to define transnational multistakeholder partnerships as "institutionalized transboundary interactions between public and private actors, which aim at the provision of collective goods"[187] [188].

In complex issues involving sustainability, these modern networks of diverse and expert actors in civil society, government and business that work jointly to achieve common results while generating values for all the parties, have been branded as a new form of global governance that has promising potentials to bridge multilateral and local and domestic unilateral actions[189]. These characteristics have in fact been framed as potentially able to address the three weak points of global politics: the governance, implementation and participation deficits[190]. While bridging the nexus between multilateral and private governance efforts, multistakeholder partnerships capture a form of 'hybrid' governance. Which focuses on fora for discussion and learning on joint problem solving, sharing of best practices and self and voluntary non- legislative standards rather than only pure private form of governance[191], which is believed to lead to a more result-based type of governance. To be effective a partnership need four elements: a) effective mandate to encourage singular countries to make binding frameworks with support for strengthening capacities, capabilities and funding for alternatives to antibiotics; b) processes to report on the commitments c) capability to advocate for the issue; and d) the abilities to mobilise all the key stakeholders [192].

More in specific, multistakeholder partnerships capture the deliberate coordination of the different interested players -such as government, international organizations, non-governmental organizations,

[185] HLPE on Multistakeholder Partnerships, FAO, 2018 (MW863).
[186] Polman P. (2016). An introduction to multi-stakeholder partnerships
[187] Pattberg, P., & Widerberg, O. (2016). Transnational multistakeholder partnerships for sustainable development: Conditions for success. Ambio, 45(1), 42-51.
[188] Schäferhoff, M., Campe, S., & Kaan, C. (2009). Transnational public-private partnerships in international relations: Making sense of concepts, research frameworks, and results. International Studies Review, 11(3), 451-474.
[189] Rochford, C., Sridhar, D., Woods, N., Saleh, Z., Hartenstein, L., Ahlawat, H., ... & Cassels, A. (2018). Global governance of antimicrobial resistance. The Lancet, 391(10134), 1976-1978.
[190] Ibidem
[191] Ibidem
[192] Ibidem

civil society and the private sector-, and sectors -which in the case of AMR, represent the sectors of health, pharmaceuticals, agriculture, trade, education and the environment -. This, to jointly achieve a goal and exploit opportunities in ways that achieve greater impact than if otherwise addressed alone by the single actors[193]. A partnership can operate in different forms: it can include horizontal collaboration across sectors, as well as vertical collaboration across levels. Vertical collaboration can be at any level, from local to global, and it includes from on-the-ground practitioners to central policymakers' actors, achievable through both top-down and bottom-up approaches[194]. Horizontal collaboration across government departments and nongovernment actors can be supported through activities such as knowledge-sharing platforms and multi-stakeholder forums for dialogue and learning and includes minor, as well as major, sector stakeholders[195].

Generally, multistakeholder partnerships tend to operate at the global level trying to tackle single development issues to make change across regions and countries. However, a number of them are increasingly focusing at country level seeking to tackle multiple development issues in an integrated way (the horizontal collaboration)[196]. Operating at the local level, partnership are more able to take fully into account the local contexts and grasp all the variables of an area, thus being able to build a more tailored solution to the country specific needs and resources available (bottom-up way), which in the case of AMR would be optimal. Some partnerships are trying to combine both the global (to achieve scale) with the local (to be locally relevant and sustainable) through "vertical integration"[197]. These partnerships tend to focus on policy advocacy, dialogue and learning, and ultimately practice change at the local level through sharing of best practices and knowledge and voluntary standards setting.

Existing partnerships that are turning towards the issue of sustainable AMU are the GASL and the Livestock Antimicrobial Partnership (LAMP)[198]. GASL brings together hundreds of stakeholders from all parts of society involved in the livestock value chain to have a better, integrated understanding of all the controversial facets generated from the sector, exchange expertise, generate learning and provide. The main objective of GASL is to strengthen society's commitments towards sustainable livestock production practices and policies and contribute in a tangible way to the attainment of the Sustainable Development Goals of the Agenda 2030. GASL is trying to address AMR risks in an integrate way with other sustainability issues including food safety and security, climate change and resources use, animal health and welfare and animals' drugs use and livelihood and economy growth.

[193] Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.
[194] Polman P. (2016). An introduction to multi-stakeholder partnerships
[195] Ibidem
[196] Ibidem
[197] Ibidem
[198] http://www.livestockdialogue.org/ (accessed August 26,2020)

LAMP[199] is technical group of GASL, but it focuses exclusively on AMR risks. LAMP is committed to tackle AMR by landing practical experience and knowledge from its partners throughout the globe. The partnership focuses and collects good practices on the areas of "incentives for change", "education and training" and "animal management and livestock husbandry systems" for prudent and effective use of antimicrobials. It then analyzes and tests these practices in support of healthy and productive livestock systems.

III.III.i Multistakeholder regulation

While both national and international legal instruments can play a major role in moving the AMR agenda forward, not legally binding solution, such as the case of standards produced by multkstakeholders, can also promote multisectorial collaboration that could serve as a legal basis for tackling AMR[200].

As governmental decision-makers continue to struggle with providing adequate regulatory and policy solutions to pressing global challenges such as AMR, innovative approaches led by non-state actors like multistakeholder governance, which challenge the hierarchical state-led model of governance of risk regulation, are getting more and more importance[201]. This coalition and cooperation between different actors are in fact, optimistically, perceived to formulate more efficient and effective responses to global problems. Furthermore, they have the additional benefit of inclusion of participants of all relevant parties that have an equal say in specific and complex matters[202].

Multistakeholder networks come together to work towards a public goal as non-profit organizations[203], thereby one could argue that their rules could be conceived as soft NGOs-like standards. However, the question is far more complicated because their nature of creating and issuing rules involves groups across public-private, profit-nonprofit and academia spheres[204].

Mulsitstakeholder standards fit better in the definition of private standards, because the latter are made by non-governmental entities and private actors, such as roundtable' initiatives, non-governmental organizations, business or producer associations, and corporations or retailers. Furthermore, since demand for sustainable products, in line with the SDGs have increased, private standards adapted to regulate sustainable supply chain.

---

[199] https://www.slu.se/en/collaboration/international/slu-global/projects-and-themes/networks/lamp/#:~:text=The%20Livestock%20Antimicrobial%20Partnership%2C%20LAMP,different%20parts%20of%20the%20world. (accessed August 26,2020)

[200] Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.

[201] Pattberg, P., & Widerberg, O. (2016). Transnational multistakeholder partnerships for sustainable development: Conditions for success. Ambio, 45(1), 42-51.

[202] Fransen, L. W., & Kolk, A. (2007). Global rule-setting for business: A critical analysis of multi-stakeholder standards. Organization, 14(5), 667-684.

[203] Ibidem

[204] Ibidem

In the literature, since the scope of multistakeholder standards operating in reality includes both governmental standards as well as private initiatives the term 'voluntary sustainability standards (VSS)', rather than 'private standards', has also been suggested[205].

Multistakheolder partnership groups that are often composed of scientific and technical actors across sectors have no effective authority to render formally binding rules because they work outside the realm of nations and their enforcement systems, nor are the rules they set considered international law because governments do not formally bind themselves through explicit agreements or customary practice with partnerships[206]. Because of the broad scope of the activities, their rules tend to provide broader and general guidelines for responsible behavior on determined sustainability topic, based on principles rather than specific and detailed rules[207]. Compliance with the proposed rules is ultimately voluntary for the actors, even though sometimes the rules set by partnerships can assume a de facto binding character when a given stakeholder depends strongly on the network. However, the benefit of their principles is that a lot of stakeholders and companies that have different expertise come together leading to synergies and effective change organizational behavior for the good across systems[208]. These features often imply higher credibility than standards set from actors alone, such as for instance only private business, as well as better quality of the rules because of the high expertise and holistic views they combine for a certain problem[209]. Additionally, with the fact that also governments take active participation in the standardization of the process especially when rules require changes in domestic or international policies, the authority and credibility of such rules, become even greater[210]. States and state agencies play an active role while being embedded and constrained in the governance of the partnership, thereby negotiating their interests with non-profit associations, international organizations and private actors.

The interactions between organizations in state and non-state sectors are often complex, dense and multi-directional and multistakehodler partnership have yet to reach their full potential. In addition, their possible failure to significantly enhance participation, inclusiveness and maintain power balance in global governance also has provided critics and room for improvement[211].
However, the consequences and benefits of the guidance put forward by multistaeholder standards on the issue become particularly important and visible when parts of these recommendations are taken

[205] UNFSS https://unfss.org/home/objective-of-unfss/ (accessed September 3 2020).
[206] Steets, J. (2010). Concrete Partnership Accountability Standards. In Accountability in Public Policy Partnerships (pp. 99-169). Palgrave Macmillan, London. Chapter 5 Pp.126
[207] Wilkinson, A., Wood, G., & Deeg, R. (Eds.). (2014). The Oxford handbook of employment relations: Comparative employment systems. Oxford University Press. Chapter 2
[208] Fransen, L. W., & Kolk, A. (2007). Global rule-setting for business: A critical analysis of multi-stakeholder standards. Organization, 14(5), 667-684
[209] Ibidem
[210] Ibidem
[211] Pattberg, P., & Widerberg, O. (2016). Transnational multistakeholder partnerships for sustainable development: Conditions for success. Ambio, 45(1), 42-51.

to guide and regulate domestic law at the public and private level[212]. Legislators but also industries and the public may rely and invoke these standards in statutes, administrative instruments, judicial decisions and wider legal practices actively promoting, regulatory convergence across states[213]. The work of these partnerships incorporated into national or international law becoming therefore binding and impacting local realities in a more effective and holistic way[214].
Overall, multistakholder standards are driven by two objectives mainly: solve problems more effectively and gain public confidence and legitimacy[215]. With the main role, remaining to assist member institutions in implementing, reinforcing or pre-empting missing and unresolved norms in policy area linked to globalization at the local level.

Potential trade effect of multistalkeholder standards

At international level, concerns have been expressed regarding the proliferation of private or multinetwork standards in any form in trade transactions. A chief argument against these norms is that they can be deleterious for some countries for accessing some markets, especially for LMICs where the resources are too little in order to comply with the high costs and high investments on technical capacity and expensive technologies required by these standards[216]. It could be argued that in multistakeholder partnerships that aim at finding sustainable solutions for everybody such as GASL, least-developed countries are generally more included in the decision-making procedures that lead to the establishment of principles and measures towards global risks. Nonetheless, sometimes these countries participation in such procedures is limited because the cost for participation in such decision-making processes is high and unaffordable[217].

Besides some potential trade negative effects, multistakeholder standards have a greater potential to enhance the facilitation of trade because they can induce faster global harmonization of norms compared to national and multilateral public standards that require extensive negotiations. Additionally, they can access multiple supply chain and domains of sector, which in the problem of AMR, it has been noted being of particular importance[218].

Regarding international trade law, it governs public standard setting bodies thus private standards as private norms set by several actors -in which sometimes some governments are present but with very limited involvement and power- would not be subject to WTO disciplines. However, during the years

[212] Kanetake, M. (2017). Transnational standards in the domestic legal order: authority and legitimacy.
[213] Ibidem
[214] Steets, J. (2010). Concrete Partnership Accountability Standards. In Accountability in Public Policy Partnerships (pp. 99-169). Palgrave Macmillan, London. Chapter 5 Pp.126
[215] Ibidem
[216] Hobbs, J. E. (2010). Public and private standards for food safety and quality: international trade implications. Estey Journal of International Law and Trade Policy, 11(1753-2016-141207), 136-152.
[217] Chea, L., & Pierola, F. (2016). The Question of Private Standards in World Trade Organization Law. Global Trade & Cust. J., 11, 388.
[218] Hobbs, J. E. (2010). Public and private standards for food safety and quality: international trade implications. Estey Journal of International Law and Trade Policy, 11(1753-2016-141207), 136-152.

the use of private standards has led to intense discussions in different for of the WTO: The Committees on TBT and SPS Measures (Article 13 notably if SPS measures are addressed). It will be thus of importance to examine the effects of multistakeholder standards on trade disciplines more exhaustively in the next chapter.

PART III WTO LAW WITH THE DIFFERENT AMR GOVERNANCE MODEL TO REGULATE AT AMR RISKS AT STAKE

To establish the efficacy of the various governance mechanisms emerged from the literature to address AMR risks in all his aspects and domains, while protecting the international commerce and economic interests within the livestock food chain, the WTO law must be analysed. Being the WTO, the only international organisation dealing with the rules of trade between nations, its primordial goal is to ensure free, efficient and predictable trade flows across the globe[219]. At the heart of WTO there are many agreements tackling different trade issues, negotiated and signed by the trading countries part of the organisation and ratified by their parliaments.

In order to examine the consistency of the various governance mechanisms with WTO laws, the first question should be addressed is which WTO Agreement apply with each motioned risk associated to AMR and AMU.

WTO Agreements are categorized into three aspects: goods, services and intellectual properties. Among the Agreements the GATT, the SPS and TBT are relevant in the issue of AMR[220][221][222]. The GATT is of importance because trade in goods (like animal derived products) are subject to the Agreement. Regarding the SPS and TBT, they are two Agreements laying down requirements for trading goods involving standards of food safety, animal and plant health and products standards. With the issue at stake in this thesis, the SPS is relevant because it sets disciplines regarding animal, plant and human health and environment protection. The TBT is also important because it governs technical measures related to animal welfare farming practices and some to human health risks that might be related to AMR.

Once discussed the applicability of the three Agreements in more detail, the research continues with the analysis of the main provisions of the Agreements for each governance approach analysed in this thesis, where they apply, and conformity assessment. Key principles of WTO law are analysed: non-discrimination, international standards, and avoidance of unnecessary barriers to trade with unilateral measures and the use of non-governmental standards. The analysis illustrated in this chapter is subdivided as follow: 1) for each Agreement its applicability with the three approaches (multilateral, unilateral and multistakeholder private standards-like measures) is discusses; 2) the discussion follows with the analysis of the main provisions; 3) preliminary conclusions on each finding are drawn.

[219] WT O (2013). Agreement establishing the World Trade organization.
[220] GATT. General Agreement on Tariffs and Trade 1994
[221] The Agreement on Sanitary and Phytosanitary Measures
[222] The Agreement on Technical Barriers to Trade

III.I Applicability of the GATT

The GATT lays down primary principles, rights, and obligations that each WTO Member upholds for trade in goods. Based on the principles that the GATT establishes, there are two additional specific Agreements dealing with i) food safety, and "animal and plant health and safety", ii) products standards in general, which are the SPS and TBT respectively. Regarding goods, the GATT Agreement applies to any measure imposed on trade, including customs duties, charges, and rules in connection with imports and exports[223].

Within the three governance approaches analysed in this thesis, the GATT applies to the EU unilateral provisions because tailored to WTO Member legislative activities. Under the GATT, Member countries' commitments include, among other provisions, non-discrimination and market access provisions and the EU VMPs package, explained in chapter II, may have effects on import of live animal and animal sourced products. Therefore, it would fall under the scope of the Agreement.

International standards governing food safety, animal and public health are set by multilateral organizations and a network of diverse actors set multistakeholder standards, both not scope of the GATT.

III.I.i EU unilateral measures

As emerged from the literature, AMR is an issue that can lead to the infectiveness of treatments and to the uncontrolled spread of infectious diseases among many species, including the human one. Infectious diseases outbreaks come with many interconnected national law and policy issues, from national health, to economic and social security that could underpin international trade. The recent outbreak of COVID-19 is a compelling example that has clearly highlighted the little resilience of international supply chains and the inability of global trade cooperation in similar sanitary crises[224]. In such circumstances, with the aim to protect public health, often countries tend to adopt a variety of export and imports restrictions on goods and services that can go against the main principles of GATT. Trade restrictions for instance might violate quantitative prohibition as prescribed by GATT Article XI[225] [226]. What is hence interesting to analyse is whether restrictions under potential pandemic crises and spreading of infectious disease can be justified under WTO law, as well whether the possible AMR threat can be compared to such pandemics. EU measures on VMPs, as pointed out by many trading partners and explained in chapter II, may lead to imports restriction on goods for counties that do not comply with EU standards on livestock production (e.g. animals that are treated with banned antibiotics for animal use in EU). Thus, EU's provisions risk being challenged against WTO disciplines.

[223] GATT (1947). General Agreement on Tariffs and Trade 1994
[224] Lapa, V. (2020). GATT Article XXI as a Way to Justify Food Prohibitions Adopted as a Response to COVID-19?. Global Trade and Customs Journal, 15(7).
[225] Ibidem
[226] GATT (1947). General Agreement on Tariffs and Trade 1994. Article XI

Main provisions

It is important to turn towards two main Articles, which the EU can assert exception under GATT in such circumstances: Article XX (b), which rules that Member States are entitled to take actions "necessary to protect human, animal or plant life or health" [227] and then links with Articles 2.2 and 5.7 of the SPS, Article XXI that lays down that a country can take actions "which it considers necessary for the protection of its essential security interests: … taken in time of war or other emergency in international relations; …"[228].

Regarding Article XX (b) the SPS Agreement incorporates the disciplines of GATT in a way that the two Agreements complement each other; it is plausible then to ask which Agreement should apply to EU measures. When a discriminatory measure falls within the application of the SPS Agreement it may fall also within the GATT, so that in principle both apply. In addition, Annex 2.4 of the SPS provides a presumption of consistency with the GATT for "measures, which conform to the relevant provision" [229]. However, two cases law make clarity on the question: *EC-hormone* case and *Australia-Salmon.* The Panel ruled that the SPS should be analysed prior to GATT and that "GATT consistency in measures found to be in conformity with the SPS Agreement"[230]. It seems therefore opportune to apply this rule also to this research; meaning that once an inconsistency is established with the SPS Agreement, then it is sufficient to observe that the EU would probably be in violation of WTO obligations and it will not be necessary to apply GATT Article XX[231]. The situation will be addressed within the scope of the SPS Agreement, point III.II of this thesis chapter.

While under the SPS Agreement (as reference to Article XX GATT) restrictive measures to protect human health must be justified by sufficient scientific evidence with a sound risk assessment or with relevant international standards, Article XXI may present a more attractive solution for unilateral measures to be justified under national security for safety and public health reasons. This because the provision relies on the ability of the country to justify trade restrictions and decide under which conditions it takes national security measures[232]. As such, Article XXI gives discretions to governments to implement measures to protect its citizens within the jurisdiction from "external threats" under "an emergency in international relations"[233]. In order to justify certain restrictive measures under Article XXI (b) (iii) there should be an emergency at the international level happening at the time the measures have been implemented[234]. "Emergency in international relations" has been defined by the

[227] GATT (1947). General Agreement on Tariffs and Trade 1994. Article XX
[228] GATT (1947). General Agreement on Tariffs and Trade 1994. Article XXI
[229] The Agreement on Sanitary and Phytosaniaty Measures. Annex 2
[230] Macroy, P.F.. J, Appleton, A. E., & Plummer, M. G. (Eds.). (2005). The World Trade Organization: legal, economic and political analysis. Springer Science & Business Media. P. 253
[231] Ibidem
[232] Lapa, V. (2020). GATT Article XXI as a Way to Justify Food Prohibitions Adopted as a Response to COVID-19?. Global Trade and Customs Journal, 15(7).
[233] GATT (1947). General Agreement on Tariffs and Trade 1994. Article XXI,
[234] Ibidem

Panel in the *Russia-Traffic in Transit* case[235], where the term was explained as "armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state"[236]. While this decision relates to determinate and established issues, it also leaves WTO Members the possibility to invoke national security given that "essential security interests" are at stake depending on a particular situation[237]. Some scholars have argued that a pandemic, like climate change risks, could be conceived as novel security threats and the term "crisis" if taken literally could indeed include situations that go beyond armed conflicts[238]. In addition, the UN Security Council has recognized that an infectious disease "constitutes a threat to international peace and security"[239], rendering possible unilateral measures against a country that brings such contagious threats.

In the case of EU and AMR, although at these stages AMR does not pose a direct and immediate threat to national security (because some antibiotics are still effective to date), like any other public good, without an effective response to the growing issue the situation will likely deteriorate leaving the human kind without room to act [240]. Bacteria that cause tuberculosis, cholera, or pneumonia can lead to catastrophic consequences, which will then trigger a lawfully national security crisis. It is however questionable whether EU measures could pass the test as of the national threat being "implemented at the time "of a crisis. In fact, even though AMR is a serious risk, from a scientific point of view a pandemic as such has not been triggered because of AMR yet. The question here would rely on whether the antibiotic crisis could be considered already in place or if a pandemic outbreak from antibiotic resistant strains should materialize to be the crisis effective in a legal term.
Some argue that the threat is no more a speculative threat for the future, but already permeating our present, with as many as 700,000 deaths per year [241], though, as in the case of COVID-19 where to date almost one billion people have died[242], it would be interesting to make light on whether a public health emergency is considered in virtue of numbers of deaths, or in virtue of exponential growth of the cases or even because we do not have an effective treatment . It could be argued that underestimating the problem now may lead to disasters in the near future with decreased effectiveness of the drugs, loss on years of achievements for the eradication of some infectious diseases and the impossibility to treat routinely medical practices.

[235] Panel Report (2019). *Russia – Measures Concerning Traffic in Transit*, WT/DS512/R, paras. 7
[236]Ibidem
[237] Zhou J. (2020). Facilitating WTO-compliant Responses to International Public Health Emergencies. International Economic Law and Policy Blog. Retrieved from https://ielp.worldtradelaw.net/2020/03/guest-post-facilitating-wto-compliant-responses-to-international-public-health-emergencies-introduct.html (accessed August 26, 2020)
[238] Ibidem
[239] Resolution 2177 (2014) Adopted by the Security Council at Its 7268th Meeting, on 18 September 2014 (United Nations Security Council).
[240] Builder, M. (2014). Antimicrobial Resistance as an Emerging Threat to National Security. Atlantic Council.
[241] UCL (2019). The Need for Global Governance of Antimicrobial Resistance retieved from https://www.ucl.ac.uk/global-governance/news/2019/jan/need-global-governance-antimicrobial-resistance (accessed August, 26 2020)
[242] Globally of 1:08pm, as CEST, 20 September 2020, there have been 30.675.675 confirmed cases of COVID-19, including 954.417 deaths, reported to WHO. WHO Coronavirus Disease (COVID-19) Dashboard retrieved from https://covid19.who.int/ (accessed September 20, 2020).

And this will have effect, as seen and experienced with COVID-19, on the health of the world's workers, economic productivity and social security [243].

As ruled in *Russia-Traffic in Transit* case, when invoking Article XXI for a national security exception, Members should give a definition of "essential security interests" and take action for the protection of essential security interests in good faith[244] . If considered this ruling, the EU could argue then that AMR, as defined in the VMPs legislation as "the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent, which is usually sufficient to inhibit or kill micro-organisms of the same species"[245] is a threat to human health, and economic development as a consequence because a pandemic disrupt value chains. In such case then AMR could be considered as an essential security interest. AMR is an external threat to the citizens and ensuring health of the workers and therefore economic activities within the state might be a legitimate reason to invoke the Article. The necessity of the rules posed by the country invoking national treatment is conceived as self-judging under Article XXI, meaning that the measure are considered necessary by the Member rather than "objective" like under Article XX[246] and is for the WTO Member to determine if it can use the exception - i.e. the EU in the VMPs package situation.

III.II Applicability of the SPS Agreement

Regarding the SPS Agreement, its scope is stipulated in Article 1 of the Agreement, which states, "This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade"[247]. As ruled by the Panel in *EC - Hormones*, two requirements have to be satisfied to invoke the SPS: a country's measures fall under the SPS and they are, directly or indirectly, affecting international trade[248]. Regarding the first rule, Article 1.2 points to Annex A where the measures are defined as meant to protect human, animal or plant life or health. The Annex further specifies that the measures apply only *within the territory of the Member*[249]. In general, the measures under the SPS aim at protecting humans and animals from food-borne (food, drinks and feed) health risks and protecting humans, animals and plants from the spreading of pests or diseases risk. Other risks that might be relevant to international trade concerning health, but also consumers information and interest protection (labelling, animal welfare etc.) are exempted from the definition, and thus they would not fall under the scope of the SPS Agreement. In a broad sense, it can be said that if a measure is not stipulated in Annex A, then the SPS is not applicable.

[243] Ibidem
[244] Panel Report (2019). *Russia – Measures Concerning Traffic in Transit*, WT/DS512/R, para. 7
[245] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.
[246] Ibidem 223
[247] The Agreement on Sanitary and Phytosaniaty Measures. Artilce I
[248] Appellate Body Report (1998). *EC - Measures Concerning Meat and Meat Products (Hormones*), WT/DS26/AB/R, WT/DS48/AB/R,
[249] The Agreement on Sanitary and Phytosaniaty Measures. Annex A

As per the second requirement (direct or indirect effect on international trade), a measure suffices to present an implication for imports that would hamper international trade such as a ban on products not in conformity with the standards of country. Following such an understanding, it is then necessary to examine the objectives pursued by every governance approach focus of this research to address all AMR risks emerged and analyse the regulative approaches, or part of them, under the SPS agreement and if in the case of unilateral measures and multistakeholder standards would fall under such Agreement .

III.II.i International standards

One of the primary aims expressed in the preamble of the SPS Agreement is the promotion of harmonized voluntary SPS standards for WTO Members with the attempt to increase free trade and reduce trade barriers caused by a plethora of different measures at the country level. WTO is not a regulatory body; thus, the organization cannot set international harmonized standards. As seen in part II, the SPS Agreement recognizes the existence of relevant international organizations for the production of harmonized standards in the domain of human, animal and plant health, specifically identified as standard setting reference bodies under the Agreement. The recognized organizations (addressed as three sisters) figure in Annex A.2, which states "international standards, guidelines and recommendations"[250] as those sets by:
1) the CAC in the area of food safety; 2) the OIE in the area of animal health; 3) the IPPC in the area of plant health; and 4) other relevant international organizations open for membership to all WTO Members, as identified by the SPS Committee, for matters not covered by the three mentioned organizations.
As the analysis of the various governance mechanisms showed, progress towards global collective action on AMR has already been made through existing international legal agreements at the multilateral level. The WHO, FAO and the OIE have created, and are currently improving, international standards for antimicrobial surveillance programmes risk management options for animal health, food safety and the environment. It is unquestionable therefore that these Codex and OIE standards are an explicit part of the SPS Agreement in the body of Article 3.4 of SPS and in Annex A.3[251], and thus part of this subchapter of the research.

Main provisions

The SPS Agreement expresses a preference over SPS measures that are based on recognized international standards because the latter encourage harmonization by means of a presumption of consistency of SPS measures conforming to international standards with the GATT and the SPS

[250] The Agreement on Sanitary and Phytosaniaty Measures. Annex A
[251] Ibidem

Agreement[252]. Nevertheless, the adoption of international standards remains on a voluntary basis for Members countries, because the level of health protection is seen as something that only a sovereign decision can deem to be appropriate for a certain country or region. The provisions regarding international standards under the SPS are laid down in Article 3 of the Agreement, where countries are provided with three autonomous options to follow in the case of AMR risks:
(a) base national SPS measures on OIE and Codex standards under Article 3.1; (b) conform measures to the cited standards under Article 3.2; or (c) deviate from the international standards, such as the case of the EU package, under Article 3.3.

Article 3.1 lays down the aim to harmonize SPS measures among countries, and as such requests Members to base their SPS measures on international standards, guidelines or recommendations where they exist. The meaning of the provision for countries SPS measures to "base on" these standards, in Article 3.1, has been interpreted by the Appellate Body in the *EC – Hormones* case, which cleared that standards set by relevant international organizations do not became mandatory under the SPS Agreement[253]. Under such interpretation, the Appellate Body stated "one thing is commonly said to be based on another, if the former stands or is founded or built upon or supported by the latter" [254] ruling that, under such provision, a national measure could adopt some, but not necessarily all elements of an international standards[255].

Regarding, the first option (a), existing Codex and OIE standards on AMR are helpful to encourage a common approach to most of the related challenges to the issue of drugs resistance, such as: Ensuring the comparability of information and data between countries as to better understand the trends of the issue and concretize scientific knowledge, and minimizing the possible differences, inequities and market distortions based on unilateral measures[256]. However, while some progress towards collective action on AMR has been reached in areas such as disease surveillance and food safety with OIE Codex standards respectively, the real achievements for consumers' health protection on the grounds have been scarce[257]. For example, a survey showed that out of 152 OIE Member States, only 27% (with lowest implementation rates in Africa (5%) and the Americas (4%)) has implemented systems for monitoring AMU in animals as laid down by Terrestrial Animal Health Code[258]. As a result, there seems to be a first real important problem with international standards: lack of compliance. States have engaged with bringing forth many actions through the decade 2010-2020, but very few

[252] The Agreement on Sanitary and Phytosaniaty Measures. Article 2
[253] Appellate Body Report (1998). *EC - Measures Concerning Meat and Meat Products (Hormones*), WT/DS26/AB/R, WT/DS48/AB/R, para 104
[254] Ibidem
[255] Ibidem
[256] Hoffman, S. J., Bakshi, R., & Rogers Van Katwyk, S. (2019). How law can help solve the collective action problem of antimicrobial resistance. Bioethics, 33(7), 798-804.
[257] George, A. (2019). Antimicrobial Resistance (AMR) in the food chain: trade, one health and codex. Tropical medicine and infectious disease, 4(1), 54.
[258] Diaz F. (2013). Collection of quantitative data on the use of antimicrobial agents. Paris: World Organisation for Animal Health . Available from: Available from: http://www.rr-africa.oie.int/docspdf/en/2013/VP/13.DIAZ.pdf (accessed August 26,2020)

have been delivered in practice and the WHO NAP failures and delays in many countries is a compelling example.
An explaining reason related to the issue could be that to reach a common goal that arises from many different risks, there is a body of international standards to turns towards to, with AMR risks tackled in a variety fields and sections of the international standards. Countries do not have sufficient resources for implementing recommended antimicrobial standards and policies. In addition, especially LMICs it is reported that they prefer to allocate the few resources they have towards primary health care issues, such as for instance in the case of vaccines and sanitation[259].

In terms of SPS Agreement, a straightforward question arises because as per the Article 3.1 the advantage of taking SPS measures based on international standards is especially important in those realities found in LMICs in which technical expertise is missing to effectively conduct scientific studies necessary to support own SPS measures, due to the little resources available in such realities. If they would base their measures on international recognized standards, they would be more likely to result in compliance with the SPS Agreement and have a better market access consequently. However there seems to be the inappropriate ambition or will to tackle AMU in both humans and animals, because the scientific evidence available is contested and generally felt as not sufficient, or most likely because countries are not politically or economically prepared to take effective actions[260].
While it is true that in theory all the countries would benefit from international coordination, most States are not willing to take their responsibilities and share their part of associated costs and trade-offs for a global good. Additionally, the cross-sectorial and interest collaboration, including human health, animal health, agriculture, food production, trade, travels and migrations distributing the risks of AMR all over different domains do not make the standardisation process at country level easier. Countries might just not be willing to engage with such hurdle[261].

A third issue is encountered with this lack of effective global action on AMR, namely important weaknesses at the multilateral level that are yet to be overcome[262]. There seems to be a suboptimal governance approach form international institutions because different bodies possess overlapping mandates towards AMR that sometimes do not align in terms of pursued objectives. For example, FAO works for increased food production efficiency, in which antimicrobial growth promoters are effectively needed; OIE stands for animal health and welfare where AMU cannot be avoided to preserve the two animal related conditions, and WHO stands for the protection of human health focusing only on reducing the risks to health. In addition to that, the organizations work through

[259] Hoffman, S. J., Bakshi, R., & Rogers Van Katwyk, S. (2019). How law can help solve the collective action problem of antimicrobial resistance. Bioethics, 33(7), 798-804.
[260] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.
[261] Hoffman, S. J., Caleo, G. M., Daulaire, N., Elbe, S., Matsoso, P., Mossialos, E., ... & Røttingen, J. A. (2015). Strategies for achieving global collective action on antimicrobial resistance. Bulletin of the World Health Organization, 93, 867-876.
[262] Hoffman, S. J., Bakshi, R., & Rogers Van Katwyk, S. (2019). How law can help solve the collective action problem of antimicrobial resistance. Bioethics, 33(7), 798-804.

different fora attended by different actors (e.g. countries representatives of agriculture vs representative of health) leading to challenging cooperation and coordination methods to change efficiently singular countries' behaviour[263]. In the absence of a consensual and integrated global action towards AMR, governments, especially those with more resources to invest in expertise and a framework, may turn towards unilateral measures with for instance direct financing, conditionality, import and export bans or sanctions [264].

As such under the SPS Agreement Member Countries have the "autonomous right", under the last of Article 3 option (3), to diverge from Article 3.2. Such provision allows a Member to set measures that achieve a higher level of protection than the one set into the international standards, with the exception that these rules must be founded on science and be the consequence of a country's' appropriate level of protection (ALOP)[265]. As such, unilateral measure must be based on a scientific risk assessment of the health risks involved as required by Article 5 of the SPS Agreement. The Appellate Body gave two reasons for this conclusion: First, it established that Article 3.3 (last sentence) requires that *all* measures which result in a higher ALOP shall not be inconsistent with any other part of the SPS Agreement, thus also Article 5. Secondly, the footnote to Article 3.3, which defines "scientific justification", implies the need of a risk assessment requirement in Article 5.1[266]. According to the Appellate Body, the burden of proof to demonstrate that a measure would not comply with international standards relies on the country invoking an infringement with the SPS[267].

A different scenario would be in the case a Member country is not satisfied with the level of protection set in international standards, but it has no scientific justification to justify the measures that result in a higher level of protection. In such case, the SPS Agreement lays down that the WTO member could base the measures on precaution providing that the actions comply with Article 5.7 of SPS[268] (discussed later with unilateral measures). This second scenario could represent the case of AMR risks, especially AMR being prompted from human to animal through the food chain as the scientific evidence regarding the risk is much contested[269]. For instance, the risk assessment for AMR has now changed in response to research revealing the antibiotic colistine resistance, which has been found out in food producing animals, humans, animals, pets and food in more than 30 countries[270]. However, although some studies and recent discoveries affirm that the food chain might play an important role in the transmission of resistance to humans, others do not show substantial results that the food chain

[263] Ibidem
[264] Hoffman, S. J., Caleo, G. M., Daulaire, N., Elbe, S., Matsoso, P., Mossialos, E., ... & Røttingen, J. A. (2015). Strategies for achieving global collective action on antimicrobial resistance. Bulletin of the World Health Organization, 93, 867-876.
[265] The Agreement on Sanitary and Phytosaniaty Measures. Article III
[266] Wolfrum, Rüdiger, et al. (2007). WTO : Technical Barriers and SPS Measures. Brill. p. 51
[267] Ibidem
[268] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods. Chapter 6
[269] George, A. (2019). Antimicrobial Resistance (AMR) in the Food Chain: Trade, One Health and Codex. Tropical Medicine and Infectious Disease, 4, 54
[270] Ibidem

favours AMR in humans because of ingestion of food[271]. Thus, it is presumable to think that if a country would set trade restrictions that are not based on international standards, it would likely incur in insufficient scientific evidence to support its measures, unless it claims for the restrictions to be necessary to address risks to animal health from diseases-causing organisms that effective antimicrobial would prevent. If challenged against the WTO, such country would presumably turn to this second alternative under Article 3.3 provisions of the SPS Agreement. The Appellate Body held that in this second case, it should be up to the complainant country to establish that the member that choose not to use an international standard could have reached its objectives by sticking to the international standard [272].

At these stages from the analysis, it seems clear that global multilateral governance still presents gaps to address AMR in all its risks and integrity. The multilateral organizations per se do not seem to be consistent with each other, advocating for different mandates and targeting different objectives and actors, while AMR should be better considered as a whole to grasps all the inter linkages and synergies across the various domains. Some scholars have been raising the attention for a reform of the global governance mechanisms relevant to AMR. They have for instance advanced a suggestion for better dialogue between human and animal health among scientists over drivers of AMR have undermined the joint efforts [273], denouncing that leadership in the global antimicrobial governance is missing and fragmented [274]. In addition to that, international standards set from multilaterals organizations as per the stages at which they are now do not present a clear mandate to address AMR in a consistent way, leading Member countries that possess enough resources to invest in expertise and diverging from international standards. Such as is the case of the EU with VPMs package, with the possibility to invoke Article 3.3 and 5.6 of the SPS Agreement if challenged by other countries.
However, one important global response will rely on the CAC revision of its framework on AMR and the setting of new standards to "enable coherent management of AMR along the food chain", which has the potential to leave important political and economic implications for Members countries and food businesses. It will be important to analyse better these new provisions when consolidated in the near future (expected to be finalised before 2021, but probably delayed).

[271] Bennani, H., Mateus, A., Mays, N., Eastmure, E., Stärk, K. D., & Häsler, B. (2020). Overview of evidence of antimicrobial use and antimicrobial resistance in the food chain. *Antibiotics*, *9*(2), 49.
[272] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods. Chapter 6
[273] Naiki, Y. (2020). Meta-Regulation of Private Standards: The Role of Regional and International Organizations in Comparison with the WTO. World Trade Review, 1-24.
[274] ECDC (2011). Transatlantic Taskforce on Antimicrobial Resistance. Recommendations for future collaboration between the US and EU. P. 44.

III.II. ii EU unilateral measures

Moving onto the second analysed governance approach, at the unilateral level, the purpose of the EU VMPs package is indicated in the recital 3 and 37 of Regulation 2019/4[275] on Medicated Feed and recital 5 and 97 Regulation 201/6[276]. According to the texts, the EU aims at increasing animal and public health protection and the environment; treating or controlling diseases in farmed animals; improving fair competition; setting harmonised provisions for the manufacture, wholesale and advertising including labelling of veterinary medicinal products within the EU; and strengthening consumer protection against AMR through consumption of animal sourced food.
There are thus multiple and interrelated purposes that the measures aim to achieve. It is clear that indeed the ultimate objectives are within the scope of the SPS Agreement: the protection of animal health, human health through animal source food and the environment from AMR contamination. Thus, the package falls under the purpose of the Agreement.

The goals of the EU to safeguard antimicrobials within the Union may not justify the means to achieve it in the context of international trade. The Union regulation approach, through closing down borders to third countries with bans for animals or their products treated with not permitted drugs in the EU and maximum levels setting for medicated feed, is already commonly perceived as a non-tariff barrier to trade and a disguised form of protectionism. As seen in part II, many WTO members have in fact already expressed condemnatory concerns in regards[277]. The justification behind the reasoning of the EU lays on the protection of human, animal life and health, conditions that are accepted as an exception to restriction to trade under the GATT, and essential rights under the SPS Agreement. The GATT, as seen previously, does not apply because the SPS Agreement provides a presumption of consistency with the provisions of Article XX of the GATT[278]. The SPS, which sets much more clear standards sustained by scientific corroboration, is the legal instrument that best evaluates EU measures on VPM package in the context of global trade. The next section is going to analyse some structural problem with EU unilateral measures in the context of AMR and the SPS Agreement.

Main provisions

Article 2 of the SPS Agreement lays down the Agreement's aim of balancing the right of sovereign governments to respond appropriately for the protection of health within the jurisdiction and obligations to promote free trade and prevent protectionism. Regardless of whether a Member

[275] EU. (2018). Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed repealing Council Directive 90/167/EEC
[276] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.
[277] Ad Hoc Codex. Intergovernmental Task force on Antimicrobial Resistance (2018). Matters Arising from Other Relevant International Organizations (OECD, World Bank, World Customs Organization, WTO). Retrieved from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F% 2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-06%2FWD%2Famr06_04e.pdf (accessed August 26, 2020)
[278] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods. Chapter 5

country deviates from international standards or regulates an SPS area where no relevant international standards exist, under Article 2.1, WTO Members are conferred with the right to take measures necessary –recapturing the GATT- for the protection of "human or animal life or health"[279]. Such would be the case of EU with the VMPs package that has set a list of antibiotics for human use only and a limit of dosages to antibiotic administered via feed that do not yet appear regulated on international standards.

Paragraph 2 further establishes that the measures must be necessary to such purpose, based on scientific principles and not be maintained without sufficient scientific evidence[280], provisions further elaborated in Article 5.1, which rules that SPS measures are to be based on a risk assessment. Regarding this point, the Union admits that there is a growing concern sustaining the fact that the food chain could be an important niche for AMR, yet that cannot be assured with certitude[281]. Therefore there seem to be a first problem with the approach of the EU and WTO disciplines. Nevertheless, the EU could appeal to the provisions further provided by Article 2.2 that lays down two basic requirements:
1) The SPS measures have to be applied only to the extent necessary to protect human or animal or plant life or health (EU VMP package purpose); and 2) the measures have a basis on scientific evidence, unless under the exception established in Article 5.7[282]. Article 5.7 in fact stipulates that when scientific evidence is inconclusive, but still there is an indication of risk to human or animal life or health such as in the case of AMR in the food chain, members can provisionally on the basis of "available pertinent information" adopt SPS measures meanwhile seeking for additional evidence[283].

In such case, the Appellate Body in *Japan - Agricultural Products II* case has recognized this provision as reflecting the precautionary principle, or Members' reasons to set measures with precaution for the protection against health risks without having conclusive results of scientific analyses[284]. In specific, the Appellate Body identified four requirements test to be met for provisional measures to comply with Article 5.7. The measures must cumulatively: 1) be imposed in respect of a situation where "relevant scientific information is insufficient"; 2) be adopted "on the basis of available pertinent information"; 3) not be maintained unless the Member seeks to "obtain the additional information necessary for a more objective assessment of risk"; and 4) be reviewed accordingly "within a reasonable period of time". Additionally the Appellate Body held that the term "reasonable period of time" has to be interpreted on a case-by-case basis, depending on the difficulty of obtaining the scientific information and the characteristics of the provisional SPS measures, furthermore the

[279] The Agreement on Sanitary and Phytosaniaty Measures. Article 2
[280] Ibidem
[281] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC recitals 9 and 40
[282] The Agreement on Sanitary and Phytosaniaty Measures. Article II
[283] The Agreement on Sanitary and Phytosaniaty Measures. Article V
[284] Panel Report (1998). *Japan – Measures Affecting Agricultural Products* para. 943-94 137

additional information has to germinate in conducting a risk assessment[285]. The issue of AMR and EU measures in respect, seems to comply with the 4 requirements test: information regarding AMR in the food chain is to date insufficient to make a certain assessment, the EU is adopting the measure on the base of pertinent information and it is seeking for additional information, and the EU will revise its measures.

The EU makes an explicit reference to the latter Article, interpreted by the Union as precautionary principle, which can be found in recital 40 of the new Regulation 2019/6[286]. The Union for instance also invoked the precautionary principle in "*EC-Hormone*" where the Union sought a level of protection higher than the one set in international standards to protect consumers' health from food safety concerns with meat products treated with carcinogenic hormones. In the context of AMR in the food chain though, it is questionable whether the EU will achieve to justify its conditions in terms of EU consumers higher vulnerability to the harmful substance. A structural problem with AMR in fact is that the issue is not something static and potentially confinable within geographic borders (as it instead could have been the case with administered hormones, but rather a dynamic process with cross-borders variables involved), e.g. environment, wildlife vectors, travellers[287]. It seems presumable to think that it will be harder in this case for the Union to prove the causal-chain model established by the Appellate Body in *EC-hormones* (from residues in food to exposure to observable effect) if the causal link gets longer and more easily disrupted due to the complexities involved in AMR in the food chain such as wildlife vectors, millions of travellers crossing national borders every day.

Moreover, paragraph 3 of Article 2, mirroring the Chapeau of Article XX GATT, stipulates that SPS measures: 1) shall not discriminate between members where and identical or similar condition prevail, and 2) do not constitute a disguised restriction of trade[288]. In *Australia–Salmon*, the Appellate body has established two indicators that define whether there is disguised restriction of trade at stake: 1) there is no risk assessment at all 2) and arbitrary or unjustifiable discrimination [289].
It can be argued that AMR is a worldwide condition and it can be thus assumed the EU's potential discrimination against most of the member of the WTO. In fact, if AMR can be perceived as a common public good worry, infectious diseases epidemiology and the variance of strains of infectious agents vary between countries, and with that the dosages and choice of certain molecules for treatments to face infectious diseases[290]. Those countries, which are affected by different epidemiological variables, might result ending up being treated less favourably than those that have the same environmental and

[285] Ibidem
[286] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC recital 40
[287] WHO,WHIPO,WTO. (2016).Antimicrobial resistance- a global epidemic. Background paper for the Technical Symposium on Antimicrobial Resistance: How to Foster Innovation, Access and Appropriate Use of Antibiotics? Prepared by the Secretariats of WHO, WIPO and WTO
[288] The Agreement on Sanitary and Phytosaniaty Measures. Article II
[289] Appellate Body Report (1998). *Australia — Measures Affecting Importation of* Salmon WT/DS18/RW 162, 174–176
[290] EURONEWS (2018). New EU rules will force Australian farmers to choose between treatment or trade. Retrived from https://www.euronews.com/2018/10/29/new-eu-rules-will-force-australian-farmers-to-choose-between-treatment-or-trade-view (accessed Augst, 26 2020)

epidemiological conditions of Europe. In its risk assessment the EU would have to take into account specific differences between countries as required by Article 5.2 of the SPS[291].
In relation to the epidemiological trends of infectious disease and variables affecting them, another structural problem with the EU approach is that local supply chains and production systems in every part of the world change and are diverse depending on the production factor that adapt to a certain geographical region and local level. The risks affecting production are also different consequently. The EU might not be aware of all the risks that are present in other countries just because the animal husbandry conditions and systems are different. Furthermore, the EU would not be lawfully entitled to control animal husbandry practices in other jurisdictions; therefore, it will be difficult for the Union to ensure that animals are treated with the standards set by its new package. As a matter of example, Australia does not use many antibiotics but relies more on good animal management practices and animal welfare conditions to boost animal health and animals' immune systems against infectious agents. However, the country argues that certain antibiotics when infectious diseases occur cannot be avoided, because essential treatment to cure animals[292][293].

To continue, Article 3 of the SPS Agreement stipulates that members be presumed to be consistent with the provision of the Agreement if the measures adopted are in line with international standards and guidelines. In the context of AMR, as analysed, Codex standards CXC 61-2005 [294] and CAC/GL 2011[295](at the moment under revisions) and OIE standards "to promote the responsible and prudent use of antimicrobial agents in terrestrial and aquatic animals"[296] currently are the available options to rely on for WTO members. As per now, the cited standards do not mention a list of antibiotics that are meant for human use only, such as the EU in Regulation 2019/6[297], neither had they set maximum limit of drugs for medicated feed in Regulation 2019/4[298]. Nevertheless, the EU has recurred to the provisions set in paragraph 3 of the same Article 3, which stipulate that, if based on scientific justification, WTO Member may set higher standards than those specified by relevant international organizations[299]. In such case, the EU should ensure that the risk proclaimed by AMR to human and animal life or health exists and is based on scientific evidence. As for now, the EU does not possess this information; rather, it recognizes in the recital 50 of the new Regulation that the current state of

[291] The Agreement on Sanitary and Phytosaniaty Measures. Article 5
[292] Ibidem
[293] Ad Hoc Codex. Intergovernmental Task force on Antimicrobial Resistance (2018). Matters Arising from Other Relevant International Organizations (OECD, World Bank, World Customs Organization, WTO). Retrieved from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F% 2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-06%2FWD%2Famr06_04e.pdf (accessed August 26, 2020)
[294] CAC (2005). Code Of Practice To Minimize And Contain Antimicrobial Resistance
[295] CAC (2011). Guidelines For Risk Analysis Of Foodborne Antimicrobial Resistance
[296] OIE (2019). Terrestrial Animal Health Code
[297] EU. (2018). Regulation (EU) 2019/6. Implementing Acts, list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans (Article 37 (5))
[298] EU. (2018). Regulation (EU) 2019/4.Delegated Acts, maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed (Article 7 (3))
[299] The Agreement on Sanitary and Phytosaniaty Measures. Article III

knowledge at Union level still lacks additional evidence[300]. Yet, as evidence continues to emerge, the spreading of AMR via the global food chain has the potential to undermine consumer health and confidence and generate negative reaction to globalisation, thus the EU stresses that it is of primary importance to continue with the collection of data[301]. However, if the EU was to be challenged and given a reasonable period to conduct a risk assessment, it is arguable to believe that it will achieve to gather enough documentation in the near future to sustain its measures. Especially if considered that the Union is already active on data gathering since the establishment of the European One Health Approach in 2011.

In addition it is worth considering that, the EU, as permitted in paragraph 4 of Article 5, by setting its SPS measures to an ALOP at zero health risk for EU consumers banning the use of certain drugs, may not result in compliance with the requirements of the subsequent paragraph of Article 5.6. The provision, in fact, determines that members shall avoid setting measures no more trade-restrictive than required achieving the ALOP established by a country. A footnote to of SPS further specifies: "For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade" [302].
In the *Australia–Salmon* case, where Australia posed measures banning, on health grounds, imports of salmon not treated with certain standards, the Appellate Body established a test that should be applied to assess whether measures are necessary with three cumulative elements:
(a) The alternative offered is significantly less restrictive; (b) the alternative offered is reasonably available to the regulating WTO member; and (c) whether it is equally efficient as the privileged option[303]. In the literature, some less burdensome measures to reach the EU ALOP could exist, including for instance transparent testing control regimes to detect antibiotics, like regulated with other food safety risks, such as pesticides detection or infectious diseases in animals[304]. That would provide essential information for both exporting countries and domestic markets and the possibility to regulate "antibiotic free" certification schemes[305].

Overall, the SPS rests the major binding instrument in order to establish whether a country's unilateral measures are in line with international trade in the context of public and animal health. For instance, the mind-set of the European Union is certainly progressive and forward-looking in order to tackle exhaustively the important issue of AMR in public health. The new VMPs package poses modern and

[300] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC recital 50
[301] Ibidem
[302] The Agreement on Sanitary and Phytosaniaty Measures. Article V
[303] Appellate Body Report (1998). *Australia — Measures Affecting Importation of* Salmon WT/DS18/RW
[304] George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.
[305] Ibidem

innovative rules, which for the first time take into consideration also the important role of the food chain in the context of AMR. Nevertheless, the Union's unilateral measures possess some structural problems within the SPS Agreement that might go against its provisions: currently there is not substantial scientific evidence to support zero risk measures and it seems that for instance the EU will recur to the precautionary principle protection in case it will be challenged under the WTO law. Secondly, bans posed by a WTO Member such as the EU, could result, as being discriminant as other less restrictive methods, such as testing for antibiotic organisms, would prove to be effective to reach the Member ALOP. Although the EU package, together with new scientific evidence, might evolve before it applies in 2022, as for now, unilateral measures on AMR could be perceived as a disguised barrier to international trade.
The EU ambitions in AMR are undoubtedly noble, but the current regional-confined approach adopted does not seem to be the most efficient to control AMR globally given the cross-border nature of the issue of AMR. It is not clear whether banning products treated with certain drugs would stop the threat at the EU level, as AMR can be transferred through not easily controllable vectors such as travellers, wildlife and the environment. Additionally, the legislation mainly tackles AMU at veterinary sector level, but other AMR issues are left unaddressed in the present package: such waste management, use of antibiotics in plants and use of antibiotics in humans. As some trade partners expressed concerns, the Union, or single countries, should engage in serious international cooperation and expertise sharing, this could prove to result much more effective in terms of AMR global surveillance in order to reinforce food safety, public health and trade.

III.II. iii Multistakeholder standards

It has been noted in part II that standards set by multistakeholder partnerships, with some degree of difference, can be perceived as private like standards set by a wider range of actors rather than just private entities. Multistakeholder standards on AMR can set requirements governing, on a voluntary basis, transactions among parties to pursue certain objectives with aspects that are important for consumers and the society as whole. Such as ensuring food safety, promoting good animal husbandry and manufacturing practices to reduce the use of drugs and animal welfare issues through multi fragmented and cross-countries supply chains for food products. These types of standards often serve the purpose to fill the gaps left by public regulations or other international standards as a way to achieve higher levels of economic, social and environmental sustainability and promote better protection level against AMR, while however impacting markets and national cross-border transactions.

When governments are participating in such organisations of actors, these standards can be subject, to some extent, to the scrutiny of the public sector, generally represented in the partnership as a group or

cluster of stakeholders; however, other multistakeholder networks are not subject to the public sector's approval.

In such case, the legal matter regarding the requirements on sustainability set by multistakehodler partnership, intended as non-governmental actors, relies in understanding whether the SPS makes provision for the regulation of such standards, since WTO being an international treaty deals only with standards and schemes set by international standards-setting bodies and those adopted by governments.

The use of multistakeholder standards may especially have implication for LMICs, which in general have been against the idea of using trade as a mean to achieve the SDGs[306] . Since these countries see WTO rules as a way to facilitate market access, the standards are often perceived as a hurdle to achieve such an objective. However, there is also the pressure to undertake measures to ensure that their exports are environment-friendly[307].

If the SPS is analysed, indeed most provisions (preamble and the basic rights, obligations in Article 2) refer to WTO Members suggesting that the SPS Agreement deals only with trade measures s of WTO Members. Annex A.1.of the SPS Agreement sets that SPS measures "include all relevant laws, decrees, regulations, requirements and procedures" applied for the purpose to protect human, animal, or plant life or health within the territory of a Member[308]. Article 1 of the Agreement lays down that SPS measure must be set and applied in accordance with its measures, however from the provisions set from Article 1 to 12, the measures do not directly address non –governmental standards. Thus, it is unclear whether SPS measures implemented by non-public networks, such as GASL, would have implication and obligation under the Agreement and within the WTO[309].

The provisions' meaning and scope have long been debated in the SPS Committee[310]. If considered Annex A.1, legal scholars have given different interpretation. Some argue that only measures set by governments fit within the definition because the terms '" law, decrees and regulation'" refer to governmental measures and thus "requirements" and "procedures" should also be considered in the same scope[311]. In addition, it has been noted that all past GATT/WTO panel reports interpreted these terms, under Article III.4 of the GATT, as requiring some degree of government involvement[312]. In fact,

[306] Negi, A. (2020). The World Trade Organization and Sustainability Standards. In Sustainability Standards and Global Governance (pp. 39-59). Springer, Singapore.
[307] Ibidem
[308] The Agreement on Sanitary and Phytosaniaty Measures. Article Annex A
[309] Prevost, D. (2008). Private sector food-safety standards and the SPS agreement: challenges and possibilities. South African Yearbook of International Law, 33(1), 1-37.
[310] Chea, L., & Pierola, F. (2016). The Question of Private Standards in World Trade Organization Law. Global Trade & Cust. J., 11, 388.
[311] Herwig, A. (2016). The Application of the SPS Agreement to Transnational, Private Food Standards. European Journal of Risk Regulation, 7(3), 610-616.
[312] Du, M. (2018). WTO Regulation of Transnational Private Authority in Global Governance. International & Comparative Law Quarterly, 67(4), 867-902.

in the *EC - Biotech* the Panel required an SPS measure to take the legal form of a law, decree or regulation, and thus SPS measures can only be government measures[313].
Additionally, scholars also argue that if the SPS Agreement is considered in light of regulatory scope as to achieve balance between sovereign of Member countries and protect health of their citizens and protectionism under the guise of the Agreement, then mutistakeholder standards, considered as private, would not fall within this scope as not designed to motivate protectionism among countries[314].

However, other scholars interpret, in line with the Appellate Body in *Australia-Apples* case ruling, that the words "include" and "all" suggest the implication of more an expansive list Annex A.1 that could include other measures beyond governmental ones, such as private mulstistakeholder standards[315]. In addition, it is noted that the Appellate Body concluded that measures that cannot be considered laws, decrees, and regulations might constitute SPS measures when they are "relevant" to the purpose of the Agreement, to protect human, animal, or plant life or health, within the territory of the Member that applies it[316][317].
In regard to the question on the objective of the SPS Agreement, it has been argued that another possible effective interpretation is that the SPS Agreement was established with the scope to guide the development of SPS measures. This to minimize their effects on trade and to eliminate all unnecessary barrier to trade, and thus the SPS recognizes the importance to especially assist LMICs with little resources to comply with the SPS[318][319] . Multistakeholder standards may be less burdensome to apply for small businesses when national or international standards are too rigid and require high technologies and expertise, thus they may fall within the scope of the Agreement[320]. For such reason Van de Zee argues that non-national standards that aim at protecting human, animal or plant life or health from pests, diseases, disease-carrying or –causing organisms, and food-borne risk in the territory of the WTO Member may fall within the scope of Annex A.1[321], although it is not a convincing argument because international standards, supposed to be the basis for compliance under Article 3.1 of the SPS, arguably also assist LMICs to comply for instance through the Codex and become part of the SPS Agreement (and possibly be vetted under Article 5.1).

[313] Prevost, D. (2008). Private sector food-safety standards and the SPS agreement: challenges and possibilities. South African Yearbook of International Law, 33(1), 1-37.
[314] Du, M. (2018). WTO Regulation of Transnational Private Authority in Global Governance. International & Comparative Law Quarterly, 67(4), 867-902.
[315] Arcuri, A. (2013). The TBT Agreement and private standards. In Research handbook on the WTO and technical barriers to trade. Edward Elgar Publishing.
[316] Appellate Body Report (2010). *Australia-Measures Affecting the Importation of Apples from New Zealand (Australia–Apples),* WT/DS367/AB/R, para 175
[317] Van Der Zee, E. (2018). Disciplining private standards under the sps and tbt agreement: A plea for market-state procedural guidelines. Journal of World Trade, 52(3), 393-414.
[318] Ibidem
[319] Du, M. (2018). WTO Regulation of Transnational Private Authority in Global Governance. International & Comparative Law Quarterly, 67(4), 867-902.
[320] Ibidem
[321] Van Der Zee, E. (2018). Disciplining private standards under the sps and tbt agreement: A plea for market-state procedural guidelines. Journal of World Trade, 52(3), 393-414.

This situation of unclear interpretation might not necessarily materialize in international trade dispute if multistakeholder food standards on AMR, or part of them, are governmentally recognized to meet quality specifications and transposed in a national legislation[322]. Alternatively, in other word a country would copy a solution developed by musltistakeholde standards into official national standards. As such it has been established in WTO jurisprudence that private standards if endorsed or connected to governments actions, may be then attributable to a WTO Member[323]. The Panel held in *Japan-Film* that actions taken by a private body could be attributed to a WTO Member if there is sufficient degree of governmental involvement, in GATT[324]. If a WTO Member for instance would base its national measures on AMR developed multistakeholder standards and more sustainable solutions on AMR than national measures, then the measures could be attributed to the WTO Member that has taken the guidance to draft national standards in line with general principles of state responsibility. Thus. If a multistakeholder standard is deemed to become a governmental public standard through some form endorsement or possibly a significant failure to regulate food safety, then the WTO Member will be fully responsible for its compliance with the WTO disciplines.

Another situation would be where actions by private-like standards cannot be attributed to the Member. In such case, within the SPS, another key Article to look at for reference to non-governmental entities is Article 13, which states: "Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories…comply with the relevant provisions of this Agreement…. Members shall not take measures, which have the effect of requiring or encouraging such regional or nongovernmental entities to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement"[325]

This Article opens the floor to some questions in the case of multistakeholder standards. The first question to look at is whether multistakeholder partnership or network would fall within the definition of "non-governmental" entities because if so, WTO Members have a legal obligation to ensure that the provision complies with the SPS Agreement. The meaning of the term is not defined in the Agreement and WTO cases law do not offer much guidance in regards.

A narrow interpretation of the term is generally based on the understanding that non-governmental entities must have a degree of government involvement [326] [327]. Which would be the case for

[322] Herwig, A. (2016). The Application of the SPS Agreement to Transnational, Private Food Standards. European Journal of Risk Regulation, 7(3), 610-616.
[323] Panel Report (1998). *Japan – Measures Affecting Consumer Photographic Film and Paper*, WT/DS44/R, para. 81.
[324] Ibidem
[325] The Agreement on Sanitary and Phytosaniaty Measures. Article Article 13
[326] Prevost, D. (2008). Private sector food-safety standards and the SPS agreement: challenges and possibilities. South African Yearbook of International Law, 33(1), 1-37.

mulstistakheolder standards being in a sense under the scrutiny of certain governments that often form part of the partnership, as member alone or groups of governments. The Appellate Body has noted the purpose of a government as: "the essence of government is that it enjoys the effective power to regulate, control, or supervise individuals, or otherwise restrain their conduct, through the exercise of lawful authority"[328]. .The term "private body" describes something that is not "a government or any public body'". Thus, by exclusion it could be argued that if an entity does not have authority to regulate lawfully is to be consider non-governmental[329]. Multistakeholders actions on AMR have primarily the scope to set guidance and principles for the public sector to set regulatory actions but should not be considered as regulatory themselves. Thus, they could be considered within the scope of non-governmental entities and would then not a priori be excluded, under Article 13, from the scope of application of the SPS Agreement.

A second issue to look at, assuming that multistakeholder standards are within the scope of Article 13, is that the Article asks WTO Members to take "reasonable measures as may be available to them to ensure that non-governmental entities within their territories"[330] comply with the Agreement.
A legal question would be to understand what are the "reasonable measures" that Members are required to take since no legal definition of such term is given. The Appellate Body stated that the term "reasonable" implies "a degree of flexibility that involved consideration of all circumstances of a particular case" [331] to be decided on a case-by-case basis depending on the issue at stake. The Appellate Body also specified that a measure is not "reasonably available" in the context of Article XIV(a) GATS , where it is "merely theoretical in nature, for instance, where the responding WTO Member is not capable of taking it, or where the measure imposes an undue burden on that Member, such as prohibitive costs or substantial technical difficulties"[332] .

The last sentence of Article 13 requires States to take measures to ensure that the non-governmental entities comply with the relevant provisions of the SPS. Scholars argue that Article 13 tone is quite relaxed if compared to Article 2.2 of the Agreement, and therefore it should be considered an obligation of conduct and best-off only requiring a minimum level of effort by a government, not result [333]. The purpose of the Article has been interpreted as a requirement for States to ensure the compliance of non- governmental standards with SPS the Agreement, but not in every single instance of the discipline. In such case, measures that are "reasonable" would include governance by soft law

[327] Herwig, A. (2016). The Application of the SPS Agreement to Transnational, Private Food Standards. European Journal of Risk Regulation, 7(3), 610-616.
[328] Appellate Body Report (1998). *Canada — Measures Affecting the Importation of Milk and the Exportation of Dairy Products*, para 97
[329] Smit, M. (2013). The applicability of the SPS agreement to private standards (Doctoral dissertation, University of Pretoria).
[330] The Agreement on Sanitary and Phytosaniaty Measures. Article Article 13
[331] Appellate Body Report (2001). *Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan*, WT/DS184/AB/R, para 84
[332] Appellate Body Report (2005*). United States-Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US-Gambling*), WT/DS285/AB/R, para 308
[333] Herwig, A. (2016). The Application of the SPS Agreement to Transnational, Private Food Standards. European Journal of Risk Regulation, 7(3), 610-616.

instruments. Typical functions of soft law would include open and flexible standard-setting process by mulstakehodler initiative for voluntary basis by and also informal implementation mechanisms relying on peer pressure and social dynamics [334] to prompt members "or other users" 's behavioural changes on a number of sustainability activities on AMR risks. Thus, mulstiastekholder standards would not serve States to steer the drafting of laws to ensure a full transposed into national laws and compliance with the SPS Agreement, rather they would serve as a dissemination of information to supply States for the purpose of assessing regulatory compliance with the SPS.

However, in the absence of a specific authoritative regulation attributing the application of private and multistakeholder standards to WTO members, it is not straightforward to assume that these types of requirements could effectively be subject at all to the SPS Agreement and to interpret what it entails for governments and other standard-setter. Article 1.1 seems to not to explicitly exclude private standards adopted for health and safety issues from the scope of the Agreement and the actual requirements of WTO Members under Article 13 still leave questions open.

III.III Applicability of the TBT Agreement

The general scope of TBT Agreement is laid down in Article 1, which defines the Agreement applicable to "technical regulations", "standards" and "conformity assessment procedures" as defined in Annex 1[335]. Its applicability is thus determined by whether regulations or standards are regarded to be the technical barriers as defined in Annex 1 of the Agreement, and not covered by the SPS Agreement. According to Annex I a technical regulation differs from a standard because its compliance is mandatory, while standards' compliance is on a voluntary basis for Member countries. Conformity assessment procedures that include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combination; are used to determine whether a TBT measure conform to established technical regulations/standards. According to the Appellate Body in *EC – Sardines*, a measure is assessed through a three parts test to establish whether it can be considered a technical regulation as defined in Annex I of the TBT:

(a) The document applies to an identifiable product or group of products; (b) the document must lay down one or more product characteristics; and (c) compliance with these characteristics must be mandatory[336].

[334] *Naiki, Y. (2020). Meta-Regulation of Private Standards: The Role of Regional and International Organizations in Comparison with the WTO. World Trade Review, 1-24.*
[335] The Agreement on Technical Barriers to Trade. Article 1
[336] Appellate Body Report (2002). *European Communities – Trade Description of Sardines ("EC – Sardines")* WT/DS231/AB/R, paras. 189-195

National authorities, international authorities as well as non-governmental organizations can administer technical regulations, standards, and conformity assessment, therefore the TBT Agreement rules and disciplines can be applied to various actors at different levels, differing slightly depending on the regulatory governance type. The measures are applied for an open list of legitimate policy objectives, for instance human health and safety (not scope of the SPS Agreement), consumer, environmental, animal protection etc. The TBT Agreement has a thus a wide field of application and it is then necessary to examine the objectives of the two governances approaches on AMR analysed in this thesis that might fall under the TBT to assess whether they would fall under the TBT: the EU unilateral measure and private multistakeholder standards.

III.III.i EU unilateral measures

The EU package on VMP 2018 sets rules for VMPs and medicated feed use to control diseases in farmed animals, improve fair competition, set harmonised provisions for the manufacture, wholesale of veterinary medicinal products within the EU and strengthen consumer health protection and increase animal and public health protection against AMR[337][338].

While the protection of animal, human and environmental health from consumption of animal sourced food with antibiotic residues and food waste from treated animals fall under the SPS Agreement's scope as assessed previously, it could be argued that protection of human health because of safeguarding of certain antimicrobials for human use only (not hence through consumption of contaminated food) would fall outside the scope of the SPS. The TBT states in Article 1.5 "The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures"[339]. Indeed, if Annex A.1 of the SPS Agreement is read carefully no mention of human health protection from diseases with an aetiology different from food and drink born and animal transmitted diseases is cited. Instead the issue could be a TBT measure as established in the preamble of the Agreement and in Article 2.2, which set forth a non-exclusive list of legitimate objective that leave Members regulatory discretion to accomplish domestic policy goals regarding human, animal and plant life and health, national security, the environment, consumers, and prevention of deceptive practices.

A legal question to address therefore would be whether both SPS and TBT Agreement are applicable if the objectives served by unilateral measures are within the scope of both Agreements. An answer to the question can be found in Article 1.5 of the TBT, which lays down the mutual exclusive relationship between SPS and TBT Agreements. An interpretation of the provision would be that the TBT

[337] EU. (2018). Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed repealing Council Directive 90/167/EEC
[338] EU. (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.
[339] The Agreement on Technical Barriers to Trade. Article 1

Agreement does not apply when some purposes of a national measure are within the scope of the SPS. Said in other words the SPS- takes precedence over the TBT Agreement[340].

The Panel in *EC-Biotech* reversed the interpretation of the Article; as such, it stated that the provision could be interpreted as that both Agreements may be applied if several sub-measures can derive from a single measure. This interpretation would then allow WTO Members to regulate risks with multiple objectives (reducing AMR because of food consumption and antimicrobials conservation for human infection diseases)[341]. According to this ruling, protecting humans by conserving essential antibiotics could then be considered a separate requirement to serve an independent purpose under the EU package. However, it can be argued that the Panel's approach cannot be applied in the case of EU measures. The separate requirements to conserve antibiotics do not serve an overall independent purpose in the measures. First of all because it is left on a voluntary basis for Member States, and not everywhere in EU the goal would be reached, and second the final objective of the package is to reduce overall AMR, which sums the action of reducing the consumption of contaminated food and the use of antibiotics both in veterinary medicine. In light of these points, it could be then concluded that TBT Agreement is not applicable in the case of EU unilateral measures.

It is important to point out however that as illustrated, the risks to human health from not having availability of therapy choices and from consumption of food and water with residual drugs are just few factors among multiple considerations from AMR. In fact, within the whole issue there are a variety of intermediate steps that would need to be solved to tackle the risks consistently with regulations. As explained in Part II of this thesis, these issues can be tackled in other bodies of legislation, which are not the scope of this thesis, but that However would expose a WTO member to the disciplines of the TBT Agreement, such as best husbandry practices with official controls in the EU, animal welfare standards and food products information with antibiotic free labels if they were to happen to cite a few.

III.III.ii Multistakeholder standards

As noted above with the SPS section as only governmental measures fall under WTO disciplines, private standards do not qualify, in principle, as rules of WTO Members because established by not qualified governmental actors. Nevertheless, multistakeholder partnerships that are trying to govern the issue of AMR besides treating the issue of public and animal health because of the infectiveness of antimicrobials to cure medical conditions, also serve the purpose to protect the other interrelated policy issues of AMR. These include animal welfare and reduction of emission through improved animal health conditions, human rights to food and health and social stability of livestock keepers,

[340] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods chapter 5
[341] Ibidem

especially smallholders, and consumer interests through fair sustainable practices. TBT Agreement disciplines some of these policy issues in WTO law – the list to the TBT is open.

In such case, to apply multistakeholder standards to the TBT the first question to answer is whether multiactor networks standards could fit the definition of "standard" in Annex 1(2) of the Agreement. In order to fit the definition (a) the standard must be set by "recognized bodies", (b) it must set rules, guidelines or define characteristics for products or production methods (c) the compliance is on a voluntary basis[342]. Point (b) and (c) of the definition would be achieved by a multistakeholder partnership because their rules would describe specific production methods such as the raising animal with biosecurity techniques to avoid animal suffering, exposition to medical threat and ensure welfare conditions but also consumer interests in buying products produced through animal welfare practices. Additionally, if the multilstakeholder standards do not lay down product characteristics, they can also be assessed on whether they include terminologies, symbols or labelling requirements[343]. A logo from a partnership on AMR ensuring the sustainability of products would suffice in this case then. Lastly, regarding the point (c), multistakeholder produce voluntary standards and from this perspective, their regulatory activities can be considered as "standards" within the meaning of the TBT Agreement.

Nonetheless, would a multiactors partnership working on AMR and engaged in standardization process fall within the purpose of point (a), the standard must be set by "recognized bodies"? To date, the question cannot be completely answered as no definition that describes the feature of a "recognized body" exists nor has been defined in cases law before. Only Annex I.8 defines the term very broadly as "Body other than a central government body or a local government body, including a nongovernmental body which has legal power to enforce a technical regulation"[344]. Some legal scholars argue that the definition could include bodies that occasionally set standards to promote societal values[345]; such could be the case of a multistakehodler partnership[346]. It has also been suggested that with the Appellate Body interpretation in *US – Tuna II* of "recognized activities'" it could be suggested somehow some guidance in understanding the meaning of "recognized body"[347]: the Appellate Body held that both evidence of recognition by WTO Members and recognition by national standardizing bodies is relevant, meaning in other words, that a private standard set by a non-governmental entity in order to meet the definition of standard under the TBT Agreement would have to be recognized by WTO Members[348]. It has been argued that applying this reasoning would be highly dependent on the single case and circumstances in which the private standards are applied,

[342] The Agreement on Technical Barriers to Trade. Annex 1
[343] Van Der Zee, E. (2018). Disciplining private standards under the sps and tbt agreement: A plea for market-state procedural guidelines. Journal of World Trade, 52(3), 393-414.
[344] The Agreement on Technical Barriers to Trade. Annex 1
[345] Arcuri, A. (2013). The TBT Agreement and private standards. In Research handbook on the WTO and technical barriers to trade. Edward Elgar Publishing
[346] Ibidem
[347] Delimatsis P. (2015), 'Relevant International Standards and Recognized Standardization Bodies under the TBT Agreement' in P Delimatsis (eds), The Law, Economics and Politics of International Standardization p. 128
[348] Ibidem

together with WTO Members views and endorsement level for the of non- governmental entities [349]. Making them unlikely to fall under the TB Agreement if little government involvement is in place.

Annex 3 of the TBT established a Code of Good Practice for the Preparation (CGP), Adoption and Application of Standards which acceptance is on a voluntary basis. The key principles of the TBT Agreement are laid down in the code: avoidance of unjustifiable or unnecessary discrimination with standards set by a "standardizing body."[350] Article 4.1, like Article 13 of the SPS Agreement, sets that WTO Members have to take reasonable and available measures to ensure that non-governmental standardizing bodies within their territories accept and comply with the CGP. Regardless whether the body setting private standards has accepted the provision, it is upon the WTO Member to take measures. Like in the SPS, "non-governmental standardizing bodies" and "reasonable measures" are not defined in the TBT Agreement, while the term "non-governmental body" is defined in Annex 1 as seen previously. It has been noted that the key term of the definition to look at is "legal power". The term implies that unless a government confers legal power to a standard maker body, it does not have obligation over the actions of the non-governmental body[351]. It results that private technical standards can be attributed to WTO Members only if they gain legal effect through public law. In such case they would fall under the purview of WTO law. In *Japan – Film*, the Panel argued, "the fact that an action is taken by private parties does not rule out the possibility that it may be deemed to be governmental if there is sufficient government involvement with it"[352].

In the case that a government endorses to some degree standards elaborated by another non-governmental entity (or in other word the measure cannot be attribute fully to the member), like could be the case with multistakeholder partnerships where government are forming part of the network with some degree of decision, under Article 3 and 4 of the TBT the WTO members have an obligation of conduct "to ensure" that non-governmental standardizing bodies comply with the obligations of the TBT[353]. The responsibility of the WTO member in such case is limited to soft law instruments that do not to ensure compliance by the private standards setter with the TBT Agreement[354].

International standards

If new regulatory powers that have an international reach, such as a musltistakheholder partnership, set standards and normative benchmarks for technical regulations, WTO members may recur to such standards under the TBT Agreement. Articles 2.4 and Article 5.2 of the TBT Agreement set the

[349] Du, M. (2018). WTO Regulation of Transnational Private Authority in Global Governance. International & Comparative Law Quarterly, 67(4), 867-902.
[350] The Agreement on Technical Barriers to Trade. Annex 3
[351] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods chapter 6
[352] Panel Report (1998). *Japan – Measures Affecting Consumer Photographic Film and Paper*, WT/DS44/R para 10.56
[353] The Agreement on Technical Barriers to Trade. Article 3 and 4
[354] Van Der Zee, E. (2018). Disciplining private standards under the sps and tbt agreement: A plea for market-state procedural guidelines. Journal of World Trade, 52(3), 393-414.

requirement for Members to use the international standard as the basis of their technical regulations. Article 2.4 of the TBT sets that WTO members that unilaterally decide to intervene in an area of law covered by international standards shall base technical measures (or part of the measures) on international standards where they exist [355]. To that regards, the Appellate Body, in *EC– Sardines*, held that the term "basis" should, not contradict the relevant international standard, and " WTO members must base their measures on all, and not only some of, the parts of an international standard that are relevant to their endeavour"[356]. Subsequently, Article 2.5 sets that if these national measures conform to TBT approved international standards are then presumed not to create obstacle to international trade[357].

A problem with the TBT is that it does not define "International standards" or designate specific international standardization bodies for reference such as the SPS Agreement with the Codex, OIE and IPPS standards. The TBT only states in Annex 1 that "international standardization community" - without further definition - are entitled to prepare international standards[358]. The Agreement refers to ISO standards in its annexes to be considered as international standards under the scope of the Agreement, but if other entities were to set technical measures then it is on the Panel to decide which standardization body could fit with the Agreement.

Given the specific lack of guidance in respect, then it is plausible to ask whether mulstistakeholder partnerships like GASL that might set also technical standards to reduce AMR risks can be considered an international standardization community. A first question to address would then be how the Panel exercises discretion to decide which standardization body could fit the purpose to provide international standards. For such decision, we might refer to existing practice and WTO jurisprudence: First, the Appellate Body has been defining some characteristics of an international standard. Under the definition of the term 'standard' in Annex 1.2 the provision cites: "document approved by a recognized body", the term "standard" informs about the meaning of the term "international standard", and as a result an international body should be a "recognized body"[359]. In US– *Tuna II* the Appellate Body held that the important feature of standard-setting institutions would be that the body should have "recognized activities of standardization" [360]. A factual interpretation would be that recognized activities in standardization exists if the body disseminates information about its standardization activities, as set out by the transparency procedures of the TBT Committee Decision [361]. The Appellate Body has additionally argued that an extensive participation in the development of

[355] Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods chapter 6
[356] Appellate Body Report (2002). *European Communities – Trade Description of Sardines ("EC – Sardines")* WT/DS231/AB/R, para. 250
[357] The Agreement on Technical Barriers to Trade. Article 2
[358] The Agreement on Technical Barriers to Trade. Annex 1
[359] The Agreement on Technical Barriers to Trade. Annex 1
[360] Appellate Body Report (2002). *European Communities – Trade Description of Sardines ("EC – Sardines")* WT/DS231/AB/R, para. aras. 361, 362, and 376
[361] *Huang, C. S. (2018). The Consistency of the New EU Organic Regulation with the WTO Law.*

the technical standards may already constitute enough evidence that a body has "recognized activities in standardization". Additionally, to assess whether activities are recognized or not, of relevance seems to be also the number of the countries that take part in the development of a standard, being more likely accepted as a body if the number of WTO Members and standardization bodies is large[362]. Multistakeholder partnerships meeting these requirements could qualify under the provisions of the Article 2.4 of TBT.

Secondly, the decision of the TBT Committee helps in providing some guidance in understanding further whether the case could be applicable. The decision sets six principles to be observed cumulatively when a body makes international standards: transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries. This decision results particularly burdensome with the requirements that decision-making should be done through consensus[363], which has been criticized because consensus is not always considered a good criterion for sustainability standards like the one of multistakeholder partnerships[364]. Multi stakeholder partnerships like GASL may recommend that decision-making procedures should be made through for consensus, but if not be reached, other alternatives could be also valid, such as voting.

It results then that if one of the multistakeholder partnerships becomes of particular relevance to set standards in the field of sustainable livestock practices could be classified as an "international body", being in compliance with many of the requirements established above. In such case national government may take the standard, shape unilateral measures on them, and result in the least restrictive option to achieve the determinate objective of AMR.

[362] Appellate Body Report (2002). *European Communities – Trade Description of Sardines ("EC – Sardines")* WT/DS231/AB/R, para 390
[363] Arcuri, A. (2013). The TBT Agreement and private standards. In Research handbook on the WTO and technical barriers to trade. Edward Elgar Publishing
[364] Ibidem

PART IV CONCLUSIONS

Since their discovery, antibiotics have underpinned modern medicine and agricultural practice. The availability of these drugs is of fundamental importance for many, saving life of millions and improving yields. Nevertheless, the uncontrolled misuses have amplified the natural occurrence of AMR, making common bacteria normally easily treatable become fatal.
While it is sure that antimicrobials are losing action power because of direct use on individuals (being humans or animals), a second scientific hypothesis for AMR dissemination is becoming increasingly apparent: AMR per ingestion of food with antibiotic residues. Common agreement has been reached that, regardless the national contexts, AMR can be the result of complex and integrated livestock value chains that spread all over the globe thanks to both humans and environmental factors. The challenge touches upon different sector across national borders, and active governance has thus emerged as a crucial attribute towards the resolution of the issue.

In many countries and at international however lack of financial resource, as well as political will and sometimes corruption hamper much the resolution progress. As a global common good, safeguarding antimicrobials and their effectiveness should be the responsibility of everybody. This could be classically achieved with multilateral governance mechanisms at the global level through non-binding regulatory instruments or at the national level with unilateral measures with binding values. What is more partnerships governance with civil societies and business are emerging, securing support through soft law instruments to produce effective change.

International standards developed by recognized organizations (Codex and OIE) are the result of global governance. Such standards offer nimble and flexible options to countries for complying with AMR rules adapting to local priorities. They provide legal and political significance under WTO because reference standards to comply with if unilateral measures have to be implemented on the issue of food safety, public health and technical standards. Nevertheless, they lack strength of pure binding mechanisms, as WTO member can deviate from the standards with some –albeit unclear- scientific evidence that justifies the measures. Furthermore, international standards are slow to be developed and updated because of the divergent political interests of the countries and the various organizations that play a heavy role, and AMR is a ticking bomb that cannot wait. Finally, multilateral governance fails to grasp the fundamental interdependence of the many sectors that AMR affects.

As per unilateral governance, the example of the EU, which is the most progressive political area in the world in terms of AMR, has been analysed in this thesis. Unilateral measures can pose modern rules that are binding for the country and hold the countries accountable for a transnational issue such as

AMR. Nevertheless, single countries alone cannot address AMR, because an issue with transnational features is unlimited to national borders. In addition, substantial scientific evidence on AMR in the food chain to support zero risk measures such as in the case of EU new VMPs package does not exist, thus unilateral measures might be challenged under WTO law as a disguised barrier to international trade. Although EU VMPs package tackles only livestock food products, animal, and public health, AMR goes beyond the livestock and public health issue, making unilateral measures potentially very segmented across different body of national legislations, which renders the resolution of the issue much more complicated at unilateral level, with the additional potential to expose the national, measure to various WTO Agreements. Ultimately, it worth mentioning that from the analysis, unilateral measures during a pandemic might be justified under national security issues. Nevertheless, scientifically the questions whether AMR is already a national security issue rests open.

This thesis wants to argue that given the flaws that the two classic governance mechanisms have shown in addressing an important and pressing issue such as AMR, multistakeholder approaches might be the ideal solution. Multistakeholder solutions would make anybody participating actively in the discussion and steer change from the local to the international level. This, across different sector and subcategories of sector with a proper One Health approach, without having to address the various issue interrelated to AMR in different fora (human health vs agriculture) and in different bodies of law. Furthermore, being multistakeholder solutions soft instruments, they can be update continuously as new scientific evidence arises without having to be bound to burdensome political debates and having to be ratified by governments. As per international trade multistakeholder standards are unlikely to fall under the provision of the Agreement, unless countries would directly transposed the solution developed by the standards and make them legally binding under national law, or unless a multistkeholder partnership would get enough important to be recognized as an international standards maker under the TBT. In such case countries could adopt unilateral measures based on transnational measures that would render the AMR tackled more homogeneously globally.

What is worth asking by now after having experience the results of a pandemic that as paralyzed the entire globe such as COVID-19, is if the humankind is ready to experience another pandemic that might arise from a bacteria worse than COVID-19. As such, if AMR feels like a future problem, in reality its consequences are already visible.
The 2020 pandemic should provide inputs to learn a lesson and grasp opportunities to build back better and resilient sustainable food systems making everybody accountable and changing old systems that have shown not to be ready in such circumstances. A starting point would be with the right governance approach that would call for holistic actions such as new and innovative partnerships, serious international cooperation and expertise sharing across all the mentioned sectors.

This means that for instance attempts to address the global threat of AMR can glean lessons from other challenging global issues whose consequences are already being perceived, like climate change. Where, despite continuous awareness of its future severity sufficient political and collective action is missing just like AMR. Learning from failure to address climate change, even though very little related to AMR, could result beneficial for many global threats that are pressuring the human existence and need a reform in global governance.

BIBLIOGRAPHY

Ad Hoc Codex. Intergovernmental Task force on Antimicrobial Resistance (2018). Matters Arising from Other Relevant International Organizations (OECD, World Bank, World Customs Organization, WTO). Retrieved from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-06%2FWD%2Famr06_04e.pdf (accessed August 26, 2020)

Adeyi, O. O., Baris, E., Jonas, O. B., Irwin, A., Berthe, F. C. J., Le Gall, F. G., ... & Shriber, D. E. (2017). Drug-resistant infections: a threat to our economic future. World Bank Group, Washington, DC.

Amtenbrink, F., Prévost, D., & Wessel, R. A. (Eds.). (2018). Netherlands Yearbook of International Law 2017: Shifting Forms and Levels of Cooperation in International Economic Law: Structural Developments in Trade, Investment and Financial Regulation (Vol. 48). Springer. Chapter 8 p 238

Appellate Body Report (1998). Canada — Measures Affecting the Importation of Milk and the Exportation of Dairy Products, para 97

Appellate Body Report (1998). Australia — Measures Affecting Importation of Salmon WT/DS18/RW

Appellate Body Report (1998). EC - Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R

Appellate Body Report (2002). European Communities – Trade Description of Sardines ("EC – Sardines")
WT/DS231/AB/R

Appellate Body Report (1998). Canada — Measures Affecting the Importation of Milk and the Exportation of Dairy Products

Appellate Body Report (2005). United States-Measures Affecting the Cross-Border Supply of Gambling and Betting Services (US-Gambling)

Arcuri, A. (2013). The TBT Agreement and private standards. In Research handbook on the WTO and technical barriers to trade. Edward Elgar Publishing.

Baral, P., Danik, M. E., & Hoffman, S. J. (2019). Leçons tirées de dix pays sur la réglementation des antimicrobiens pour les animaux d'élevage. Canadian Journal of Law & Society/La Revue Canadienne Droit et Société, 34(3), 521-553.

Bennani, H., Mateus, A., Mays, N., Eastmure, E., Stärk, K. D., & Häsler, B. (2020). Overview of evidence of antimicrobial use and antimicrobial resistance in the food chain. Antibiotics, 9(2), 49.

Bengtsson, B., & Greko, C. (2014). Antibiotic resistance—consequences for animal health, welfare, and food production. Upsala journal of medical sciences, 119(2), 96-102.

Bloom, D. E., & Cadarette, D. (2019). Infectious disease threats in the twenty-first century: strengthening the global response. Frontiers in immunology, 10, 549.

Breeman, G., Dijkman, J., & Termeer, C. (2015). Enhancing food security through a multi-stakeholder process: the global agenda for sustainable livestock. Food Security, 7(2), 425-435.

Brouwer, J. H., Woodhill, A. J., Hemmati, M., Verhoosel, K. S., & van Vugt, S. M. (2015). The MSP guide: How to design and facilitate multi-stakeholder partnerships. Centre for Development Innovation Wageningen UR.

Bruno, A. V., & Mackay, C. (2012). Antimicrobial resistance and the activities of the Codex Alimentarius Commission. Revue scientifique et technique (International Office of Epizootics), 31(1), 317-323.

Builder, M. (2014). Antimicrobial Resistance as an Emerging Threat to National Security. Atlantic Council.

CAC (2005). Code Of Practice To Minimize And Contain Antimicrobial Resistance

CAC (2011). Guidelines For Risk Analysis Of Foodborne Antimicrobial Resistance

CAC (2012). Code of practice for fish and fishery products. Code of practice for fish and fishery products

CAC (2018). Proposed Draft Revision Of The Code Of Practice To Minimize And Contain Foodborne Antimicrobial Resistance (CXC 61-2005) retrieved from http://www.fao.org/fao-who-

codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-06%252FWD%252Famr06_05e.pdf (accessed August 26,2020)

CAC (2018). Proposed Draft Guidelines On Integrated Monitoring And Surveillance Of Foodborne Antimicrobial Resistance retrieved from http://www.fao.org/faowhocodexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-06%252FWD%252Famr06_06e.pdf (accessed August 26,2020)

CDC. Zoonotic diseases. Retrieved from https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html
(accessed August 24, 2020)

Centres for Disease Control and Prevention (US). (2019). Antibiotic resistance threats in the United States, 2019. Centres for Disease Control and Prevention, US Department of Health and Human Services. Retrieved from https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
(accessed August 24, 2020)

Chea, L., & Pierola, F. (2016). The Question of Private Standards in World Trade Organization Law. Global Trade & Cust. J., 11, 388.

Collignon, P. (2015). Antibiotic resistance: are we all doomed?. Internal medicine journal, 45(11), 1109-1115.

Collignon, P., Beggs, J. J., Walsh, T. R., Gandra, S., & Laxminarayan, R. (2018). Anthropological and socioeconomic factors contributing to global antimicrobial resistance: a univariate and multivariable analysis. The Lancet Planetary Health, 2(9), e398-e405.

Danik, M. E., Baral, P., & Hoffman, S. J. (2018). De la ferme à l'assiette mondiale: Dix approches à la réglementation des antimicrobiens chez les animaux d'élevage. In C. Régis, L. Khoury, & R. P. Kouri (Eds.), Health law at the frontier (pp. 121–172). Montreal, Canada: Éditions Yvon Blais.

Delimatsis P. (2015), 'Relevant International Standards and Recognized Standardization Bodies under the TBT Agreement' in P Delimatsis (eds), The Law, Economics and Politics of International Standardization p. 128

Diaz F. (2013). Collection of quantitative data on the use of antimicrobial agents. Paris: World Organisation for Animal Health . Available from: Available from: http://www.rr-africa.oie.int/docspdf/en/2013/VP/13.DIAZ.pdf (accessed August 26,2020)

Du, M. (2018). WTO Regulation of Transnational Private Authority in Global Governance. International & Comparative Law Quarterly, 67(4), 867-902.

Duckenfield, J. (2013). Antibiotic resistance due to modern agricultural practices: an ethical perspective. Journal of agricultural and environmental ethics, 26(2), 333-350.

EC (2017). A European one health action plan against antimicrobial resistance (AMR). European Commission.

ECDC (2011). Transatlantic Taskforce on Antimicrobial Resistance. Recommendations for future collaboration between the US and EU. P. 44.

Economou V., Gousia P. (2015). Agriculture and food animals as a source of antimicrobial-resistant bacteria, Dove Medical Press, pp.49-61

EU (1998). Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes. Official Journal L, 221(08), 08.

EU (2001). Community Strategy against Antimicrobial Resistance.

EU (2003). Regulation 1831/2003/EC on additives for use in animal nutrition, replacing Directive 70/524/EEC on additives in feeding-stuffs.

EU (2013). Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC

EU (2013). Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. Off. J. Eur. Union, 226, 1-17.

EU (2016). Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

EU (2018). Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed repealing Council Directive 90/167/EEC

EU (2018). Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.

EURONEWS (2018) New EU rules will force Australian farmers to choose between treatment or trade. Euronews.com. last access 03/04/2020

European Court of Auditors (2019). Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU.

FAO (2009). Global Agriculture Towards 2050

FAO (2012). FAO Statistical yearbook 2013: World Food and Agri-culture. Rome: Food and Agriculture Organization of theUnited Nations. Retrieved from http://www.fao.org/docrep/018/i3107e/i3107e00.htm. (Accessed August 24, 2020)

FAO. (2016.) Action Plan on Antimicrobial Resistance. Rome: FAO

FAO (2018). The future of food and agriculture, alternative pathways to 2050. Retrieved from http://www.fao.org/3/I8429EN/i8429en.pdf (accessed August 26,2002)

FVE (2016). Relationship between animal welfare and the use of antibiotics in food animals. doc/063. Retrieved from https://www.fve.org/cms/wp-content/uploads/063-FVE_AWW-Position-on-resistance-and-animal-welfare_final.pdf
(accessed August 26, 2020)

Fransen, L. W., & Kolk, A. (2007). Global rule-setting for business: A critical analysis of multi-stakeholder standards. Organization, 14(5), 667-684.

GATT (1947). General Agreement on Tariffs and Trade 1994

Gawas, V. M. (2017). Doctrinal legal research method a guiding principle in reforming the law and legal system towards the research development.

Gerber, P.J., Steinfeld, H., Henderson, B., Mottet, A., Opio, C., Dijkman, J., Falcucci, A. & Tempio, G. (2013). Tackling climate change through livestock – A global assessment of emissions and mitigation opportunities. Food and Agriculture Organization of the United Nations (FAO), Rome.

George, A. (2018). Antimicrobial resistance, trade, food safety and security. One health, 5, 6.

George, A. (2019). Antimicrobial Resistance (AMR) in the Food Chain: Trade, One Health and Codex. Tropical Medicine and Infectious Disease, 4, 54

Ghosh, D., Veeraraghavan, B., Elangovan, R., & Vivekanandan, P. (2020). Antibiotic resistance and epigenetics: more to it than meets the eye. Antimicrobial agents and chemotherapy, 64(2)

Gruszczynski, L. (2010). Regulating health and environmental risks under WTO law: a critical analysis of the SPS agreement. OUP Oxford. Chapter 3 P. 76

Hathaway, S. C. (2013). Food control from farm to fork: implementing the standards of Codex and the OIE. Rev Sci Tech Oie, 32, 479-485.

Herwig, A. (2016). The Application of the SPS Agreement to Transnational, Private Food Standards. European Journal of Risk Regulation, 7(3), 610-616.

HLPE on Multistakeholder Partnerships, FAO, 2018 (MW863).

Hobbs, J. E. (2010). Public and private standards for food safety and quality: international trade implications. Estey Journal of International Law and Trade Policy, 11(1753-2016-141207), 136-152.

Hoffman, S. J., Caleo, G. M., Daulaire, N., Elbe, S., Matsoso, P., Mossialos, E., ... & Røttingen, J. A. (2015). Strategies for achieving global collective action on antimicrobial resistance. Bulletin of the World Health Organization, 93, 867-876.

Hoffman, S. J., Bakshi, R., & Rogers Van Katwyk, S. (2019). How law can help solve the collective action problem of antimicrobial resistance. Bioethics, 33(7), 798-804.

Holmes AH, Moore LS, Sundsfjord A, et al (2016). Understanding the mechanisms and drivers of antimicrobial resistance. Lancet; 387: 176–87

Huang, C. S. (2018). The Consistency of the New EU Organic Regulation with the WTO Law

HUTCHINSON, T. 2017. Doctrinal research: Researching the jury. In: WATKINS, D. & BURTON, M. (eds.) Research methods in law. Routledge, 7-33.

Inoue, H., & Minghui, R. (2017). Antimicrobial resistance: translating political commitment into national action. Bulletin of the World Health Organization, 95(4), 242.

Kanetake, M. (2017). Transnational standards in the domestic legal order: authority and legitimacy.

Kumarasamy, K. K., Toleman, M. A., Walsh, T. R., Bagaria, J., Butt, F., Balakrishnan, R., ... & Krishnan, P. (2010). Emergence of a new antibiotic resistance mechanism in India, Pakistan, and the UK: a molecular, biological, and epidemiological study. The Lancet infectious diseases, 10(9), 597-602.

Lattanzi A. (2017). Antimicrobial resistance related to food production: International cooperation and EU action. Rivista Diritto Alimentare. Anno XI, numero 2

Lapa, V. (2020). GATT Article XXI as a Way to Justify Food Prohibitions Adopted as a Response to COVID-19?. Global Trade and Customs Journal, 15(7).

Macroy, P.F.. J, Appleton, A. E., & Plummer, M. G. (Eds.). (2005). The World Trade Organization: legal, economic and political analysis. Springer Science & Business Media. P. 253

McEwen, S. A., & Collignon, P. J. (2018). Antimicrobial resistance: a one health perspective. Antimicrobial Resistance in Bacteria from Livestock and Companion Animals, 521-547.

Naiki, Y. (2020). Meta-Regulation of Private Standards: The Role of Regional and International Organizations in Comparison with the WTO. World Trade Review, 1-24.

Negi, A. (2020). The World Trade Organization and Sustainability Standards. In Sustainability Standards and Global Governance (pp. 39-59). Springer, Singapore.

OIE (2011). Guidelines on veterinary legislation.

OIE (2016). OIE annual report on the use of antimicrobial agents in animals. Better understanding of
the global situation.

OIE (2017). Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

OIE (2017). Terrestrial Animal Health Code. Aquatic Animals Health Code

OIE (2017). Terrestrial Animal Health Code

OIE (2020). Covid-19 portal. Retrieved from https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/
(accessed 26 August, 2020)

OIE (2020). Intenrational standards. Retrieved from https://www.oie.int/en/for-the-media/amr/oie-amr-standards/ (avvessed on August 26, 2020)

O'Neill J. (2015). Antimicrobials in agriculture and the environment: reducing unnecessary use and waste, Review on Antimicrobial Resistance, p. 1

O'Neill J. (2016). Tackling drug-resistant infections globally: final report and recommendations— the review on antimicrobial resistance. Retrieved from https://amrreview.org/sites/default/files/160525_Final%20paper_with%20cover.pdf (accessed August 20, 2020).

Orand, J. P. (2012). Antimicrobial resistance and the standards of the World Organisation for Animal Health. Revue Scientifique et Technique-OIE, 31(1), 335.

Panel Report (1998). Japan – Measures Affecting Consumer Photographic Film and Paper, WT/DS44/R

Panel Report (1998). Japan – Measures Affecting Agricultural Products, WT/DS76/R

Panel Report (2019). Russia – Measures Concerning Traffic in Transit, WT/DS512/R

Pattberg, P., & Widerberg, O. (2016). Transnational multistakeholder partnerships for sustainable development: Conditions for success. Ambio, 45(1), 42-51.

Petros C. Mavroidis. (2016). The Regulation of International Trade, Volume 2 : The WTO Agreements on Trade in Goods.

Prevost, D. (2008). Private sector food-safety standards and the SPS agreement: challenges and possibilities. South African Yearbook of International Law, 33(1), 1-37.

Polman P. (2016). An introduction to multi-stakeholder partnerships

Ramesh, N., Tripathi, H., Yadav, R., & Tripathi, B. N. (2018). ANTIMICROBIAL RESISTANCE (AMR): A GLOBAL THREAT TO LIVESTOCK AND HUMAN HEALTH

Resolution 2177 (2014). Adopted by the Security Council at Its 7268th Meeting, on 18 September 2014 (United Nations Security Council).

Rochford, C., Sridhar, D., Woods, N., Saleh, Z., Hartenstein, L., Ahlawat, H., ... & Cassels, A. (2018). Global governance of antimicrobial resistance. The Lancet, 391(10134), 1976-1978.

Saint, V. A., & Simpson, S. (2018). Tackling antimicrobial resistance (AMR) together. Working paper 5.0: Enhancing the focus on gender and equity.

Salimiyan Rizi, K. K., & Noghondar, M. (2018). Adaptive antibiotic resistance: Overview and perspectives. J. Infect. Dis. Ther, 6, 1-3.

Schäferhoff, M., Campe, S., & Kaan, C. (2009). Transnational public-private partnerships in international relations: Making sense of concepts, research frameworks, and results. International Studies Review, 11(3), 451-474.

Slorach, S. A. (2006). Assuring food safety: the complementary tasks and standards of the World Organisation for Animal Health and the Codex Alimentarius Commission. OIE Scientific and Technical Review, 25, 813-21.

Smit, M. (2013). The applicability of the SPS agreement to private standards (Doctoral dissertation, University of Pretoria).

Steets, J. (2010). Concrete Partnership Accountability Standards. In Accountability in Public Policy Partnerships (pp. 99-169). Palgrave Macmillan, London. Chapter 5 Pp.126

Stewart, T. P., & Johanson, D. S. (1998). The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics. Syracuse J. Int'l L. & Com., 26, 27.

The Agreement on Sanitary and Phytosaniaty Measures

The Guardian (2020). Is factory farming to blame for coronavirus? Retrieved from https://www.theguardian.com/world/2020/mar/28/is-factory-farming-to-blame-for-coronavirus (accessed August 26, 2020)

The Hill (2020). Reducing pandemic risk begins with ending factory farming. Retrieved from https://thehill.com/opinion/energy-environment/491066-reducing-pandemic-risk-begins-with-ending-factory-farming
(accessed August 26,2020)

UCL (2019). The Need for Global Governance of Antimicrobial Resistance retieved from https://www.ucl.ac.uk/global-governance/news/2019/jan/need-global-governance-antimicrobial-resistance (accessed August, 26 2020).

Vaarten J. (2012). Clinical impact of antimicrobial resistance inanimals. Rev Sci Tech. 31:221–9.

Van Damme, I. (2009). Treaty interpretation by the WTO Appellate Body. Oxford University Press on Demand.

van den Bossche, P., Schrijver, N., & Faber, G. (2007). Unilateral Measures Adressing Non-Trade Concerns. Peter Van den Bossche, Nico Schrijver, Gerrit Faber, UNILATERAL MEASURES, The Ministry of Foreign Affairs of The Netherlands

Van Der Zee, E. (2018). Disciplining private standards under the sps and tbt agreement: A plea for market-state procedural guidelines. Journal of World Trade, 52(3), 393-414.

Von Wintersdorff, C. J., Penders, J., Van Niekerk, J. M., Mills, N. D., Majumder, S., Van Alphen, L. B., ... & Wolffs, P. F. (2016). Dissemination of antimicrobial resistance in microbial ecosystems through horizontal gene transfer. Frontiers in microbiology, 7, 173.

WHO. Zoonoses. Retrieved from https://www.who.int/zoonoses/en/ (accessed August 24, 2020)

WHO, Regional Office for Europe (2011). Tackling antibiotic resistance from a food safety perspective in Europe, p. xiii.

WHO. Antimicrobial resistance. (2018). www.who.int/mediacentre/factsheets/fs194/en/ (accessed September 8, 2020).

WHO(2019). Averting the AMR crisis. What are the avenues for policy action for countries in Europe? POLICY BRIEF 32

WHO Regional office for Europe retrieved from: https://www.euro.who.int/en/about-us/whd/past-themes-of-world-health-day/world-health-day-2011-antibiotic-resistance-no-action-today,-no-cure-tomorrow/antibiotic-resistance/frequently-asked-questions (accessed August 26,2020)

WHO,WHIPO,WTO. (2016).Antimicrobial resistance- a global epidemic. Background paper for the Technical Symposium on Antimicrobial Resistance: How to Foster Innovation, Access and Appropriate Use of Antibiotics? Prepared by the Secretariats of WHO, WIPO and WTO

Wilkinson, A., Wood, G., & Deeg, R. (Eds.). (2014). The Oxford handbook of employment relations: Comparative employment systems. Oxford University Press. Chapter 2

Wolfrum, Rüdiger, et al. (2007). WTO : Technical Barriers and SPS Measures. Brill.

World Bank (2016). Drug-resistant infections: a threat to our economic future (discussion draft). Retrieved from: http://pubdocs.worldbank.org/en/527731474225046104/AMRDiscussion-Draft-Sept18updated.pdf (accessed August 26, 2020).

WT O (2013). Agreement establishing the World Trade organization.

WTO (2016). DG ROBERTO AZEVÊDO SPEECH. Retrieved from https://www.wto.org/english/news_e/spra_e/spra142_e.htm (accessed August 26, 2020)

Zhou J. (2020). Facilitating WTO-compliant Responses to International Public Health Emergencies. International Economic Law and Policy Blog. Retrieved from https://ielp.worldtradelaw.net/2020/03/guest-post-facilitating-wto-compliant-responses-to-international-public-health-emergencies-introduct.html (accessed August 26, 2020)