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An EU Touch on Global Health Norms Adopted under the Auspices of the WHO: a Field of Opportunities in a Limited Legal Landscape

by

Dominique Mollet*

Abstract

This working paper examines how the relations between the EU and WHO are arranged and how the (substantive) health norms at the two levels interact with each other. In particular, it is assessed how the EU can influence (legally binding) norms adopted under the auspices of the WHO. It is submitted that despite the restricted legal landscape, namely the lack of capacities of the EU under the WHO Constitution and the limited competences of the EU in the field of health, the EU is capable of influencing international health law adopted under the auspices of the WHO. It ensures international health norms' compatibility with its own health legislation, for instance, through coordinated positions of the Member States. Additionally, and most importantly for the purposes of this working paper, the EU actively engages in multilevel dialogues with the WHO. Thereby it uploads its own norms to the WHO-level and downloads WHO-norms to the EU-level. These 'multilevel normative processes' do not only ensure preferred international health norms for the EU, but they similarly contribute to the development of health law – both internationally and regionally.

Keywords: International health law; European Union; competences; multilevel dialogue; multilevel normative processes; uploading and downloading

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An EU Touch on Global Health Norms Adopted under the Auspices of the WHO: a Field of Opportunities in a Limited Legal Landscape

I. International health law and the EU

Caught by the Covid-19 pandemic, the world is committed to adopt a new legal instrument concerning pandemic prevention, preparedness and response under the auspices of the World Health Organization (hereinafter WHO).[1] These negotiations will take place in the complex system of modern global health governance: where the WHO was at the centre of all global health matters once, the system now consists of a more expansive ecosystem.[2] New relevant actors have entered the stage and relations among actors have changed. In the case of the European Union (hereinafter EU), WHO norms can no longer simply be implemented at the national level, but the norms' compatibility with EU law must first be ensured. Accordingly, this also means that at the WHO-level, EU interests must now be promoted and protected, either by the Member States or by the EU itself.

Unsurprisingly, this complexity also applies in the context of the newly launched negotiation process. The EU has demonstrated significant interests to join the negotiations and become a Party to the final instrument. In fact, it was Charles Michel, the President of the European Council, who coined the idea of a new International Pandemic Treaty.[3] On 20 May 2021, the Council adopted a decision prescribing the common position of the Member States, so as to ensure that the EU will be able to accede to the treaty.[4]

This involvement and eagerness in the development of an international legal instrument in the policy area of health may come as a surprise, as, at first sight, the EU does not appear

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[1] *World Health Assembly agrees to launch process to develop historic global accord on pandemic prevention, preparedness and response, World Health Organization*, 1 December 2021, available at https://www.who.int/news/item/01-12-2021-world-health-assembly-agrees-to-launch-process-to-develop-historic-global-accord-on-pandemic-prevention-preparedness-and-response (consulted on 15 January 2022); *Special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response* (2021) WHA74(16).

[2] GOSTIN Lawrence and Others, *Reimagining Global Health Governance in the Age of COVID-19* AJPH (2020) pp. 1615-1619, p. 1617.

[3] *Press release by President Charles Michel on an international Treaty on Pandemics, European Council*, 3 December 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/12/03/press-release-by-president-charles-michel-on-an-international-treaty-on-pandemics/ (consulted on 1 October 2021).

[4] Art. 1 of Council Decision 2021/1101 of 20 May 2021 on the position to be taken on behalf of the European Union in the seventy-fourth session of the World Health Assembly, [2021] OJ L 238/79.

to have much formal influence on international health law adopted under the auspices of the WHO: the EU only has observer status at the WHO, the reason for which it, among other things, does not have voting rights,[5] and cannot become a party to all legal instruments adopted by the WHO.[6] Additionally, the EU's competences in the field of health under its own institutional structure remain rather limited as well.[7] Nevertheless, the Union has found multiple ways to effectively influence international health law adopted under the auspices of the WHO in the past.

This working paper analyses the means by which the EU and its institutions can influence international health law adopted under the auspices of the WHO, despite the limited legal landscape. By mapping the rules that govern EU-WHO relations (i.e. the *de jure* dimension) and analyzing the content of overlapping EU legislation and international health law (i.e. the *de facto* dimension), patterns of EU action to ensure and enhance the compatibility of international health law with its own legislation are revealed.[8] This paper focuses on the concrete actions that the EU itself can directly undertake: the institutions of the Union can either prescribe coordinated positions to the Member States or the Commission itself can engage in multilevel normative dialogues. These dialogues take place between the WHO and the EU and, as argued below, are constitutive for (the substantive content of) international health law. It is argued in this paper that despite the *de jure* restricted playing field of the EU at the WHO, the Union makes great efforts and is able to influence the norms of international health law, through the use of coordinated positions of the Member States, but especially through multilevel normative dialogues.

The first substantive section commences with an analysis of the legal dimensions that govern, or restrain, EU and WHO relations. Subsequently, the practical means of influencing substantive norms set at the WHO-level are identified and discussed. Two types of interaction can be distinguished: indirect and direct interaction. The section briefly discusses how the EU can indirectly influence international health law when it is not invited to the table, namely through coordinated positions. As the focus of this paper is on direct interactions between the EU and the WHO, the analysis on coordinated positions remains concise. Rather, the second mean of influencing international health law at the WHO is more relevant for the purposes of this paper, and is therefore extensively analyzed. This phenomenon is labeled as 'multilevel normative dialogues' in this paper, and occurs through direct interactions between the EU and the WHO. For this sub-section, the theory of 'uploading'

[5] *Constitution of the World Health Organization*, signed in New York on 22 July 1946 and entered into force on 7 April 1948, signatories: 59, parties: 193, UNTC vol. 14, p. 185 (hereinafter WHO Constitution) Art. 59.
[6] WHO Constitution, cit., Art. 22.
[7] Art. 168 TFEU.
[8] Note that this method of identifying patterns does not follow theories of 'transnational legal processes', which has been defined as: '*the theory and practice of how public and private actors […] interact in a variety of public and private, domestic and international fora to make, interpret, enforce, and ultimately internalize rules of transnational law*', HONJU KOH Harold, Transnational Legal Process, Nebraska Law Review (1996) pp. 181-207, pp. 183-184.

and 'downloading' norms between different levels is applied to reveal the interactions between the EU and the WHO. These interactions are then illustrated by two case studies: the former case study focuses on the multi-level normative dialogue on novel tobacco products and the latter examines the multi-level normative dialogue regarding the measurement method for tar, nicotine and carbon monoxide levels in tobacco products. Finally, a brief conclusion is presented.

As indicated above, this paper focuses on direct interactions between the EU and the WHO. Therefore, the scope of this paper is confined to the efforts of the EU to influence international health law adopted at the WHO, while the efforts of the Member States to influence international health fall outside the scope of the paper. For this reason, the EU's 'competence' to prescribe coordinated positions of the Member States and the underlying legal dimension for such positions is identified, but is not further analyzed. Additionally, the analysis is confined to binding international health law adopted under the auspices of the WHO, such as the Regulations and Conventions. In practice, this means that the analysis is restricted to the International Health Regulations (hereinafter IHR) and the Framework Convention on Tobacco Control (hereinafter FCTC).[9] Consequently, non-binding soft law standards, such as recommendations, codes and guidelines are disregarded.[10] Lastly, the words rules norms, laws and standards are used interchangeably. [11]

II. The legal landscape of EU-WHO relations – the constitutional and institutional structures

Due to the fact that the EU has legal personality, it is competent to enter into external relations, i.e. relations with external actors.[12] Nevertheless, this does not provide the Union with a *carte blanche* to become a member to any international organization or become Party to any treaty under international law. For the specific relations discussed here, namely EU-WHO relations, there are two sources informing competences, capacities and (potential) constraints. The first concerns the constitutional structure of the WHO, which does not

[9] *International Health Regulations*, signed in Geneva on 23 May 2005 and entered into force on 15 June 2007, UNTS 2509, p. 79 (hereinafter IHR); *Framework Convention on Tobacco Control*, signed in Geneva on 21 May 2003 and entered into force 27 February 2005, signatories: 168, parties: 182, UNTS: vol. 3202, p. 166 (hereinafter FCTC). Note that when reference is made to 'the IHR' in this paper, this concerns the latest version of the IHR as revised and adopted in 2005. For a more extensive explanation on the IHR and its history, please consult, for instance NEGRI Stefania, *Communicable disease control*, *in* Burci Gianluca, Toebes Brigit (eds), "Research Handbook on Global Health Law", Cheltenham/Northampton, Edward Elgar Publishing (2018) pp. 265- 302, pp. 269-278.

[10] The exclusion of these standards is a methodological decision and should not imply that these standards are not of relevance: for reasons of topic delineation, they simply fall outside the scope of this paper. For more information on the types of non-binding instruments the WHO can adopt and their relevance, please consult: *International Regulatory Co-operation and International Organisations: The Case of the World Health Organization (WHO)*, OECD and WHO (2016) pp. 1-56, pp. 31-35. An example of such a non-binding instrument includes: *International Code of Marketing of Breast-milk Substitutes*, International Code of Marketing of Breast-milk Substitutes Geneva, World Health Organization (1981).

[11] For a more precise elaboration on the usage of such terms, please consult WESSEL Ramses, WOUTERS Jan, *The Phenomenon of Multilevel Regulation: Interactions between Global, EU and National Regulatory Spheres: Towards a Research Agenda*, *in* Follesdal Andreas, Wessel Ramses, Wouters Jan (eds), "Multilevel Regulation and the EU: The Interplay between Global, Euopean and National Normative Processes", Leiden/Boston, Martinus Nijhoff (2008) pp. 7-47, pp.11-12.

[12] Art. 47 TEU.

allow for membership by regional economic integration organizations (REIOs) and, subsequently, affects the applicability of international health law to the EU. The second relates to the internal division of competences between the EU and the Member States in the policy area of health and the external competences flowing from this division. The following section addresses the two matters accordingly, followed by an elaboration on why the EU *de facto* is interested in influencing the norms of international health law.

A. REIOs under the WHO's constitutional order

Despite the fact that the WHO has the prerogative to '*establish effective relations and co-operate closely with […] inter-governmental organizations as may be desirable*',[13] the organization is only open for full membership to States.[14] As a consequence, the EU cannot acquire full membership and holds observer status in the governing bodies of the WHO.[15] Accordingly, the EU is unable to vote, but is, among other things, empowered to attend meetings of some WHO bodies and submit memoranda to the Director-General.[16] In contrast to the EU, , the Member States are full members and thus enjoy all rights that come with membership.[17]

The WHO has broad legal competences. First of all, it is endowed with the 'authority to adopt conventions or agreements with respect to any matter within the competence of the Organization'.[18] Their adoption requires a two-thirds vote in the World Health Assembly (WHA), the governing body of the WHO, and their entry into force is dependent upon the constitutional processes of the Parties.[19] Accordingly, the instruments adopted under this provision are governed by the rules enshrined in the Vienna Convention on the Law of Treaties (VCLT).[20] This means that non-WHO Members may also become Parties to the legal instruments adopted under Article 19 of the WHO Constitution, depending on the exact specifications stipulated in the convention or agreement concerned. The only legal instrument adopted under Article 19 of the WHO Constitution thus far is the FCTC. Article 35(1) FCTC stipulates that *'[t]his Convention shall be subject […] to formal confirmation or accession by regional economic integration organizations*'.[21] Accordingly, both the Member States and the EU are Parties to the FCTC,[22] and are therefore bound by its provisions.[23] The

[13] WHO Constitution, cit., Art. 70; EMMERLING Thea, *World Health Organization (WHO) and other global health bodies: The EU voice in a fragmented global health landscape*, *in* Wessel Ramses, Odermatt Jed (eds) "Research handbook on the European Union and international organizations", Edward Elgar Publishing (2019) pp. 120-141, p. 121.
[14] WHO Constitution, cit., Art. 3.
[15] EMMERLING. cit., pp. 123-124; *Exchange of Letters between the World Health Organization and the Commission of the European Communities concerning the consolidation and intensification of cooperation (2001/C 1/04)* [2001] OJ C 1/7.
[16] *Exchange of Letters between the WHO and the Commission*, cit., D1.1-1.3.
[17] Countries, World Health Organization, available at https://www.who.int/countries (consulted on 25 September 2021).
[18] WHO Constitution, cit., Art. 19.
[19] *ibid.*
[20] *Vienna Convention on the Law of Treaties*, signed in Vienna on 23 May 1969 and entered into force on 27 January 1980, signatories: 45, parties: 116, UNTS: vol. 1155, p. 331.
[21] WHO Constitution, cit., Art. 35(1).
[22] The FCTC is thus a mixed agreement, LARIK Joris, WESSEL, Ramses, *Instruments of EU External Action*, *in* Wessel Ramses, Larik Joris (eds), "EU External Relations Law: Text, Cases and Materials", Oxford, Hart Publishing, 2nd edn (2020), pp. 101-138, pp. 122-128.
[23] *WHO Framework Convention on Tobacco Control*, United Nations Treaty Collection, available at https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=_en (consulted on 4 October 2021).

soon-to-be-negotiated pandemic prevention, preparedness and response instrument may potentially be adopted under this provision, the reason for which EU accession is not precluded.[24]

Moreover, Article 21 of the WHO Constitution stipulates that the WHA can adopt regulations concerning a number of issues, including '*procedures designed to prevent the international spread of disease*'.[25] After adoption and notification, these regulations automatically enter into force for all WHO Members, except for those who have submitted a rejection or notification within a specified period.[26] Under this provision, the IHR and the International Nomenclature Regulations have been adopted, which are therefore only applicable to WHO members.[27]

As a consequence, the EU is not a party to the IHR. Nevertheless, both the wording of the IHR itself and the Union appear to award a role to the EU as a REIO whose Member States are parties to the IHR. Article 57(3) IHR states that:

> '[w]ithout prejudice to their obligations under these regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization'.[28]

According to the Commission's reading of this provision, it implies that in case Member States no longer have competences to fulfill their obligations under the IHR, '*the EU would have to act collectively, at the initiative of the Commission*'.[29] Hence, the EU is not bound by the IHR, but accepts its obligation to contribute to the fulfillment of Member States' obligations under the IHR. In a similar fashion, it must be noted, though, that the fact that the EU cannot become a Party to regulations adopted under the auspices of the WHO does not mean that the EU does not have to take into consideration the content of their norms. Rather, as the Member States are Parties, they must abide with the norms stipulated by such WHO regulations – unless they have submitted rejections or reservations.

B. External health relations in the EU's institutional structure

The above has indicated that the EU can only become a party to agreements or conventions adopted by the WHO under Article 19 of the WHO Constitution, provided that the agreement or convention concerned allows for this. However, as the EU does not (appear to) have extensive competences in the policy area of health, the question remains whether the

[24] *An international treaty on pandemic prevention and preparedness* European Council, available at https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/ (consulted on 1 October 2021); *Special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response*, cit.
[25] WHO Constitution, cit., Art. 21(a).
[26] *ibid*, Art. 22.
[27] IHR, cit.; *World Health Organization Regulations Regarding Nomenclature (Including the Compilation and Publication of Statistics) with Respect to Diseases and Causes of Death*, signed in Geneva on 22 May 1967 and entered into force 1 January 1968, UNTS: vol. 1172, p. 346.
[28] IHR, cit., Art. 57(3).
[29] *Communication form the Commission to the European Parliament and the Council on the International Health Regulations* [2006] COM(2006) 552 final, para. 2.1.

EU is competent to accede to such agreements or conventions and implement their norms under its own institutional structure. In other words, does the Union have competences to accept legally binding obligations by acceding to a health convention? The analysis below considers how the European institutional structure informs the EU's competences to participate in the international health law-forum of the WHO. This sub-section commences with an analysis of whether the EU itself has competences to engage in external health relations, followed by a short analysis on the duties of Member States vis-à-vis the Union at international fora following the principle of sincere cooperation.

Article 216(1) TFEU states that '*[t]he Union may conclude an agreement with one or more third countries or international organisations*' and identifies four instances in which the Union may act upon this competences.[30] It may do so 1) '*where the Treaties so provide*' (i.e. explicit external competences);[31] 2) '*where the conclusion of an agreement is necessary in order to achieve, within the framework of the Union's policies, one of the objectives referred to in the Treaties*' (i.e. implicit competences);[32] 3) where a legally binding Union act requires so;[33] or 4) where it '*is likely to affect common rules or alter their scope*'.[34] The competence to accede to agreements, naturally, is governed by the principle of conferral, as laid out in Article 5 TEU.[35] Therefore, the EU does not have unlimited competences to become party to any agreement it wishes to accede to.

In the present discussion, the explicit (instance 1 above) and implicit (instance 2 above) competences are particularly of relevance. The former are explicitly stated in the Treaties, such as Article 207 TFEU on bilateral trade agreements.[36] The latter are not explicitly conveyed as external competences, but are implied from the EU's internal competences.[37] In this regard, the *ERTA*- doctrine, as ruled by the European Court of Justice (hereinafter ECJ), holds that the Union's external competences are parallel to its internal competences.[38] In other words, this means that the EU can also imply external competences from legal bases upon which it can act internally.

How does this work in the policy area of health in particular? First of all, an express external competence can be identified in Article 168(3) TFEU, which states that '*[t]he Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health*'.[39] However, the phrasing 'foster[ing] *cooperation'* implies that this

[30] Art. 216(1) TFEU; OTT Andrea, *EU External Competence*, *in* Wessel Ramses, Larik Joris (eds), "EU Exteral Relations Law: Text, Cases and Materials", Oxford, Hart Publishing, 2nd edn (2020) pp. 61-100, pp. 72-78.
[31] *ibid.*
[32] *ibid.*
[33] *ibid.*
[34] *ibid.*
[35] Art. 5 TEU.
[36] Article 207(3) TFEU states: *'Where agreements with one or more third countries or international organisations need to be negotiated and concluded, Article 218 shall apply, subject to the special provisions of this Article'*, Art. 207(3) TFEU.
[37] OTT, cit., p. 72.
[38] ECJ, Case 22/70 *European Agreement on Road Transport*, EU:C:1971:32.
[39] Art. 168(3) TFEU. Note how this provision also served as the mandate for the exchange of letters between the WHO and the Commission in 2001, EMMERLING, cit., 121.

legal basis can only be relied on for external action to a limited extent.[40] In comparison, other express external competences, such as the one on the common commercial policy in Article 207(3) TFEU, refer to the application of Article 218 TFEU, the provision that sets out the procedures to be followed in order for the Union to negotiate and conclude agreements.[41] Consequently, it must be concluded that, although the TFEU provides for an explicit competence to seek cooperation with third countries and international organizations in the field of public health, this only awards the EU with highly limited formal external competences.

Implicitly, the EU has more extensive external competences in the area of health. For example, Article 168(5) TFEU enables the European Parliament and the Council to adopt certain incentive measures, including:

> 'measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States'.[42]

In practice, this provision lied at the basis of the adoption of legislation in the field of communicable disease (CD) control, such as Decision 10822013/EU on serious cross-border threats to health and repealing Decision 2119/98/EC (Health Threats Decision, hereinafter HTD).[43] Nevertheless, and similar to what is mentioned above concerning Article 168(3) TFEU, this provision does not appear to award the EU with meaningful treaty-making powers: it can accede to an agreement to the extent that it covers '*incentive measures*'.[44]

In addition to the above, it is pertinent to emphasize that the EU is obliged to ensure *'[a] high level of human health protection […] in the definition and implementation of all Union policies and activities*'.[45] Accordingly, legislation adopted under legal bases that do not explicitly protect human health may also harmonize health(-related) policy areas. Tobacco control legislation makes an important example in this regard. Considering the economic nature of the Union, an important legal basis adhered to for the adoption of legislation (subordinately) promoting non-communicable disease (NCD) prevention is Article 114 TFEU, which aims at furthering the internal market.[46] The case law of the CJEU has confirmed that this provision can be a permissible legal basis for measures protecting human health. In the first *Tobacco Advertising* case, the Court ruled that:

> 'provided that the conditions for recourse to [Article 114] as a legal basis [is] fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health

[40] Emphasis added, Art. 168(3) TFEU.
[41] Arts. 207(3) and 218 TFEU.
[42] Art. 168(5) TFEU.
[43] Decision 1082/2013/EU of the European Parliament and of the Council of 22 October on serious cross border threats to health and repealing Decision No 2119/98/EC, [2013] OJ L 293/1 (hereinafter Health Threats Decision).
[44] Art. 168(5) TFEU.
[45] Art. 168(1) TFEU.
[46] Art. 114 TFEU.

> protection is a decisive factor in the choices to be made. On the contrary, the [first] paragraph of [Article 168] provides that health requirements are to form a constituent part of the Community's other policies and [Article 114(4)] expressly requires that, in the process of harmonisation, a high level of human health protection is to be ensured'.[47]

Article 114 TFEU (and its predecessors) has served, following this judgment, as a legal basis for numerous EU internal measures advancing public health, particularly in the field of NCD prevention, such as the Tobacco Advertising Directive, the Tobacco Products Directive (hereinafter TPD) and Directive 2002/46/EC.[48] In the latter case, it was similarly challenged whether Article 114 TFEU was the appropriate legal basis for a measure furthering health.[49] The Court upheld this Directive, thereby confirming that Article 114 can serve as a legal basis in the adoption of measures furthering health, provided that their ultimate objective is 'the *establishment and functioning of the internal market'*.[50] Following the *ERTA*-doctrine, this thus means that the EU has implied external competences in the policy area of health, provided that the content of the norms fall within the context of Article 114 TFEU.

Accordingly, the above indicates that the Union has competences to engage in external relations within the field of health. Although the explicit external competences under Article 168(3) TFEU as a basis of external relations are rather limited, implicitly there are more opportunities. Therefore, Articles 168(5) and 114 TFEU, as sources of implied external competences, are of particular importance, as they allow the EU to engage in relations with the WHO, if it has a seat around the table.

However, as indicated in the previous sub-section on the constitutional structure of the WHO, this may not always be the case. In situations of EU absence, the role of the Member States in representing the EU's voice, according to the principle of sincere cooperation, proves important.

The principle of sincere cooperation, as stated in Article 4(3) TEU prescribes that '*the Union and Member States shall, in full mutual respect, assist each other in carrying out tasks which flow from the Treaties*'.[51] This principle also applies externally, and as a consequence influences, or limits, the room for solitary actions of Member States at the international level.[52] The content of this principle has been interpreted in the jurisprudence of the ECJ in several ways, including

[47] ECJ, Case C-376/98 *Advertising and sponsorship of tobacco products*, EU:C:2000:544, para. 88.
[48] Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, [2003] OJ L 152/16 (hereinafter Tobacco Advertising Directive); Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, [2014] OJ L 127/1(hereinafter Tobacco Products Directive); Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, [2002] OJ L 83/1.
[49] *Alliance for Natural Health*, cit.
[50] *ibid*, paras. 24-43; Art. 114(1) TFEU.
[51] Art 4(3) TEU.
[52] VAN ELSUWEGE Peter, *The Duty of Sincere Cooperation and Its Implications for Autonomous Member State Action in the Field of External Relations*, *in* Varju M (eds) "Between Compliance and Particularism, Springer, Cham. https://doi.org/10.1007/978-3-030-05782-4_13 pp. 283-298 pp. 283.

that it obliges Member States to refrain from accepting obligations arising from the international level that are against EU rules when the Union is not part of the international forum concerned.[53] Similarly, Member States are also bound to safeguard EU legislation and policies at international for a when the EU is absent, so as to ensure the protection of EU law and the EU's functionality as a global actor.[54] In such situations, the EU acts 'through the medium of the Member States':[55] the Member States thus become a mouthpiece of the Union, for instance through coordinated positions.[56]

C. The importance of (influencing) international health law for the EU

The above set the rules concerning the EU's participation in international health law(making), both under the WHO's constitutional framework and its own institutional structure. Correspondingly, it has been submitted that the EU only has a limited amount of direct obligations, due to the limited applicability of international health law, and competences, due to the limited competences in the policy area of health. Accordingly, the question may rise why the EU would want to influence the normative content of international health law – especially given the Union's economic nature.

Over the past few decades, a 'multilevel normative process', of which the EU is both actively engaged in and subjected to, has been increasingly taking place.[57] This includes the process of the determination of norms at the international level, such as at the WHO.[58] Increasingly, therefore, rules find their substantive origin at different levels: at the domestic level, European level or international level. This leads to numerous 'informing combinations', meaning, for instance, that domestic rules can find their origin in European legislation or international law, but that also European legislation informing domestic rules itself be informed by international law.[59]

Accordingly, the increased, and increasingly influential, multilevel normative processes directly and indirectly influence the EU's legal order. Logically, if international health norms

[53] ECJ, Case C-45/07 *Commission v Hellenic Republic (IMO)* ECLI:EU:C:2009:81, para. 30; THIES Anne, *Principles of EU External Action*, *in* Wessel Ramses, Larik Joris (eds), "EU External Relations Law: Text Cases and Materials", Oxford, Hart Publishing, 2nd edn (2020) pp. 29-60, p. 44; VAN ELSUWEGE cit. p. 289.
[54] THIES, cit., pp. 47.
[55] ECJ, Opinion 2/91 *ILO Convention* ECLI:EU:C:1993:106, para. 36; VAN ELSUWEGE cit. p. 289; THIES cit p. 42.
[56] Note, with regard to this paragraph, that the application of this principle is contingent upon the existence of a Union competence (exclusive or shared). As this paper predominantly focuses on the EU's influence through its own representation, the principle of sincere cooperation and common positions are only touched upon to the extent necessary to illustrate the playing field. For a more elaborate explanation on the external application of the principle of sincere cooperation, please consult: THIES cit. pp. 39-47; VAN ELSUWEGE cit.
[57] WOUTERS Jan, WESSEL Ramses, FOLLESDAL Andreas, *Multilevel Regulation and the EU: A Brief Introduction*, *in* Follesdal Andreas, Wessel Ramses, Wouters Jan (eds), "Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes", Leiden/Boston, Martinus Nijhoff (2008) pp. 1-6, pp. 3-4.
[58] Although multilevel governance is a widely understood concept, its most relevant part for the purposes of this paper is the increased production of norms at the international level, and its direct and indirect influences on the EU and the Member States. WESSEL, WOUTERS, cit., pp. 10-12.
[59] For a more elaborate discussion, please consult WESSEL, WOUTERS, cit., pp. 12-21.

are, or may become, binding to the EU, the Union has a direct interest of ensuring compatibility with EU legislation, its institutional structure and its policy preferences. A good example of such an occasion includes the FCTC, a treaty which requires, among other things, the regulation of the content of tobacco products and regulation of tobacco advertising, promotion and sponsorship,[60] which had both already been regulated at the EU-level.[61]

Furthermore, this interest even persists if international health norms are not (directly) applicable to the EU itself, but have an effect on the abidance of EU norms by the Member States. For instance, the IHR affect the EU's legal order indirectly, as it is binding upon the Member States, but not upon the EU itself.[62] As a means of illustration, Article 45 IHR requires the collection of health information, which has been harmonized under EU law in, among other pieces of legislation, the General Data Protection Regulation.[63] Depending on the content of the co-existing norms at the different levels involved (i.e. the international and European levels), a clash between the two may result, which in turn may lead to a deadlock in negotiations and international health protection. Thus, this risk of colliding norms reinforces the EU's interest to safeguard the compatibility of international norms with EU legislation, even if the international norm is not directly applicable to itself.

Finally, besides the potential direct or indirect applicability of international health law to the EU, there is an additional impetus for the EU to be involved in the definition of health norms at the international level. Practice shows that even if obligations are strictly speaking only applicable to the Member States and the EU only has '*the competence to support, coordinate or supplement actions of Member States*',[64] the Union is eager to strengthen Member States' individual efforts. For instance, besides the IHR obligations in policy areas that have been harmonized under EU legislation (such as health data protection mentioned above), the EU has taken efforts to facilitate and coordinate Member States' efforts to implement the IHR. An example of this includes the obligation under Article 13 IHR to '*develop, strengthen and maintain […] the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern […]*'.[65] The EU coordinates and supports the Member States'

[60] FCTC, cit., Arts. 9, 13.
[61] Arts. 3 of Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, [2001] OJ L 194/26 (hereinafter 2001 Tobacco Products Directive); Tobacco Advertising Directive, cit.
[62] Note that the principle of sincere cooperation and the possibility for the WHO members to reject Regulations mandates EU Member States to reject obligations that go against EU law.
[63] Art. 9 of Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of data, and repealing Directive 95/46/EC, [2016] OJ L119/1. Although the current GDPR has been adopted after the latest revision of the IHR in 2005, the previous version of the GDPR adopted in 1995 already harmonized the processing of health data as well, in Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, [1995] OJ L 281/31. Another piece of EU legislation that has harmonized this includes Art. 16 of the Health Threats Decision, Health Threats Decision, cit., Art. 16.
[64] Art. 6 TFEU.
[65] IHR, cit., Art. 13.

domestic efforts by organizing consultations between the Member States and the Commission in the Health Security Committee.[66] This voluntary acquisition of tasks, to enhance processes in the Union in practice, can also constitute an important factor as to why the EU is interested in the determination of the content of international health norms.

III. The EU's means to influence international health law at the WHO

Thus far it has been emphasized that the legal structures governing EU-WHO relations prove to be rather restrictive with some (legal) opportunities, while the stakes to be involved in the development of, and influence the content of international health norms are high for the EU. Following the above description of the legal dimension, the EU may not appear to be an influential actor on the global health stage. Nevertheless, in practice, the EU proves to be capable of influencing international health law adopted at the auspices of the WHO to a great extent. The following section addresses how the EU, despite its limited legal competences, acts to influence the content of the norms adopted at the WHO, thereby promoting the adoption of norms that are favourable to the EU and its Member States. It commences with a brief explanation on how the EU can make use of coordinated positions in negotiations in which the Commission cannot represent the EU. This is followed by a description of 'multilevel normative dialogues' as a means to influence international health law. This phenomenon is illustrated with two brief case studies into the development of norms under the FCTC. These case studies clarify how the EU engages in multilevel dialogues with the WHO to ensure compatibility between EU legislation and international health norms and, as a secondary consequence, significantly contributes to the development of international health law.

A. 'Indirect' EU-WHO Interactions: Coordinated Positions

In areas where the EU itself is not involved in the development of norms, following the principle of sincere cooperation, the EU can mandate a coordinated positions, and thereby indirectly influence international health law(making). In such cases, Member States convey the coordinated position, instead of their unilateral position.[67] For instance, during the negotiations of the IHR, Portugal made a joint declaration as the presiding State in the Council, which clearly demonstrates the existence of a coordinated position:

> 'The [IHR] are a very effective tool for reinforcing the connection between the surveillance systems and in establishing rapid reaction mechanisms. The EC and its 27 Member States have strongly supported the revised IHR, which recently came into force, and we will continue this support for the implementation of the IHR in full and without restrictions'.[68]

[66] Note the explicit reference to the IHR in Article 4(1)(d) and 11 of the Health Threats Decision, Health Threats Decision, cit., Arts. 4(1)(d) and 11.
[67] EMMERLING, cit., 125-127.
[68] IHR, cit., Appendix 2 (III).

The adoption of coordinated positions stretches beyond the negotiation- and adoption-phases of international norms, and is similarly adopted in the implementation phase of international norms. For instance, during the implementation phase of the IHR, the Commission declared the need for a common approach, requiring EU-wide regulation and a Memorandum of Understanding between the EU and the WHO.[69]

In light of the ongoing pandemic and in addition to the legal pandemic prevention, preparedness and response instrument, the WHA has declared the need for amendments to the IHR. [70] It is unsure what the role of the EU will be in these forthcoming amendments. The WHO Member States Working Group stated in its report on the special session of the WHA that:

> "the way forward should include a process or processes for:
>
> i) developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response, and
>
> ii) strengthening IHR (2005), including implementation, compliance support for IHR core capacities and potential targeted amendments to the IHR".[71]

Following the interpretation of the Commission, this means that the EU will be able to negotiate on behalf of the Member States for both developing a Convention and strengthening the IHR.[72] Naturally, this cannot be decided by the EU alone, but also depends on whether the EU will be enabled to negotiate under the WHO's constitutional structure. Given Article 22 of the WHO Constitution on the adoption of Regulations, it is questionable whether the EU will indeed be able to negotiate IHR amendments on behalf of the Member States. It thus remains to be seen how this will work in practice. In theory, however, this should not make a difference as to the outcome: both the Commission and Member States, following the principle of sincere cooperation, will have to convey the EU's position.

B. 'Direct' EU-WHO Interactions: Multilevel dialogues

Besides coordinated positions, the EU also engages in technical, multi-level dialogues with the WHO. This mainly happens in instances where the EU is competent to act, both under the WHO's constitutional framework and its own institutional structure. A good example to illustrate this kind of dialogue includes the ongoing conversations between the EU and

[69] *Communication from the Commission to the European Parliament and the Council on the International Health Regulations*, cit., paras. 5 and 5.1.
[70] *Draft report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the special session of the World Health Assembly*, WHO, 12 November 2021 (A/WGPR/5/2) para. 4.
[71] Note that this has been quoted by EU institutes twice, without references, but that, importantly, the present author was unable to retrieve the original text and document online. Emphasis added, *Recommendation for a Council Decision authorising the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)*, European Commission, Brussels, 1 December 2021 (COM(2021)766 final/2), para. 1; *Special session of the World Health Assembly on pandemic preparedness and response*, Council of the European Union, Brussels, 3 December 2021 14065/21, Annex.
[72] *ibid*, Art. 1; para. 1. Note, however, that this recommendation has been downgraded on 6 December 2021.

WHO within the framework established by the FCTC. Within this framework, in which the EU and Member States both participate depending on the topic discussed,[73] the EU and the WHO continuously 'upload and download' norms.[74]

The theory of 'uploading and downloading' has mainly been considered within studies on Europeanization, thereby focusing on the uploading and downloading processes that take place between the domestic and European levels. These terms are understood in the sense that policy-making in the Union is a two-way process.[75] On the one hand, the Member States 'upload', i.e. lobby, their policy preferences to the EU-level, while on the other hand, Member States 'download', i.e. accommodate, the EU's policies to their domestic policies.[76]

These processes similarly take place in relations between international organizations, including the WHO, and supranational organizations, such as the EU. In several ways and in different stages of the policy-making process the EU and the WHO inform each other's standards (see *Figure 1*). On the one hand, the EU 'uploads' its policy preferences, by itself or through coordinated positions of the Member States. Simultaneously, on the other hand, the Union implements or facilitates the implementation of WHO standards and norms, thereby 'downloading' them.

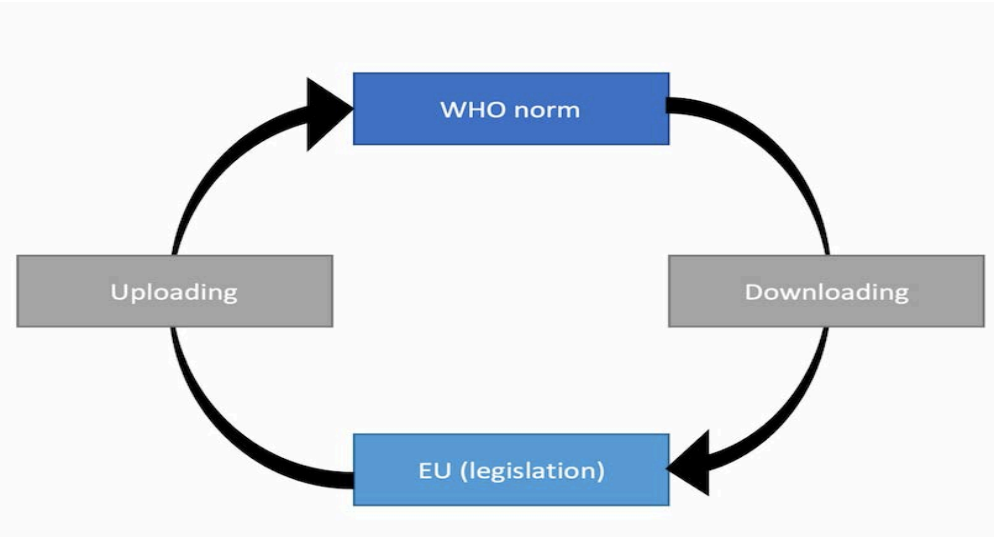

Figure 1. The uploading and downloading of norms between the WHO and the EU.[77]

[73] LARIK, Wessel, cit., pp. 122-128.
[74] This theory, explained in a different context, is discussed, among other sources, in QUAGLIA Lucia, *The European Union and Global Financial Regulation*, Oxford, Oxford University Press (2014), 4 pp. The following sources discuss the process of uploading and downloading between the EU-level and the Member State-level: VAN EERD Marjolein, WIERING Mark, DIEPERINK Carel, *Policy Discretion, Adaptation Pressure and Reloading Implementation Experiences in EU Water Governance: The Case of the Netherlands*, Water Alternatives (2019), pp. 886-906, pp. 886-889; CONOLLY, John, *Europeanization, Uploading and Downloading: The Case of Defra and Avian Influenza*, Public Policy and Administration (2008), pp. 1-25, pp. 9-11, 12-19; PRØITZ Tine, *Uploading, downloading and uploading again – concepts for policy integration in education research*, Nordic Journal of Studies in Educational Policy (2015) pp. 70-80, pp. 71-73.
[75] CONNOLLY, cit., p. 10.
[76] *ibid.*
[77] Figure inspired by, but slightly adjusted from Figure 1 in PRØITZ, cit., p. 72; BÖRZEL Tanja, PANKE Diana, *Europeanization*, *in* Cini Michelle, Pérez-Solórzano Borragán Nieves (eds) "European Union Politics", Oxford, Oxford University Press, 6th edn, (2019), pp. 115-126, pp. 119-124.

It must be emphasized here, that this process is not linear, but rather circular. In other words, the development of a norm does not necessarily commence at the WHO-level, followed by a 'download' (i.e. implementation) to the EU-level, to finally be 'uploaded' again to the WHO-level. Rather, the arrows point both ways and are not necessarily sequential.

The development of policies does not happen in a vacuum. Instead, policy initiation requires external input, namely that, for instance, a problem exists and an actor calls for the adoption of a policy to solve this.[78] This process also took place during the development of the FCTC's norms. As it increasingly became obvious in the last decades of the previous century that tobacco products seriously harm consumers, calls were made to adopt an international convention on tobacco control. [79] In response to this, the WHA launched the drafting and negotiations of a framework convention in May 1999,[80] where both Member States and Union, represented by the Commission, were present.[81] Accordingly, they ensured a large degree of compatibility, if not complete compatibility, with the EU's existing tobacco control legislation. The following table (*Table 1*), presenting an overview of phrases originating from FCTC provisions and pre-existing EU tobacco control legislation, demonstrates the level of overlap and, therewith, compatibility.

Table 1 – Overlap between FCTC provisions and pre-existing EU legislation on tobacco control

FCTC provision	**Pre-existing EU tobacco control legislation**
Article 6 – '*Price and tax measures to reduce the demand for tobacco*'[82]	Article 1(1) of the Directive 92/79/EEC
'*[…] each Party should […] adopt or maintain […] measures which may include: (a) implementing tax policies […]*'.[83]	'*Not later than 1 January 1993, the Member States shall apply to cigarettes minimum consumption taxes in accordance with the rules provided for in this Directive*'.[84]

[78] For a more extensive elaboration on policy processes from a political science perspective, please consult HEYWOOD Andrew, *Politics*, London, Palgrave Macmillan (2013) 4th ed, pp. 356-361.
[79] For more background information, please consult TAYLOR Allyn, *An International Regulatory Strategy for Global Tobacco Control* Yale Journal of International Law (1996) pp. 257-304; ZHOU Suzanne, LIBERMAN Jonathan, *The global tobacco epidemic an the WHO Framework Convention on Tobacco Control-the contributions of the WHO's first convention to global health law and governance*, *in* Burca Gianluca, Toebes Brigit (eds), "Research Handbook on Global Health Law", Cheltenham/Northampton, Edward Elgar Publishing (2018), pp. 340-388, pp. 340-342.
[80] *History of the WHO Framework Convention on Tobacco Control*, World Health Organization 2009, available at http://apps.who.int/iris/bitstream/handle/10665/44244/9789241563925_eng.pdf;jsessionid=89E9A92283CAD2A89FE55C3A5CBA2C8E?sequence=1, (consulted on 10 October 2021).
[81] Emmerling, cit., p. 133-134.
[82] FCTC, cit., Art. 6.
[83] FCTC, cit., Article 6(2)(a).
[84] Art. 1(1) of Council Directive 92/79/EEC of 19 October 1992 on the approximation of taxes on cigarettes [1992] OJ L 316/8.

Article 9 – '*Regulation of the contents of tobacco products*'[85] '*Each Party shall […] adopt and implement effective legislative, executive or other measures for such for […] [the] regulation [of the contents and emissions of tobacco products]*'.[86]	Article 3 of the 2001 Tobacco Products Directive. '*From 1 January 2004, the yields of cigarettes […] shall not be greater than:* *10 mg per cigarette for tar,* *1 mg per cigarette for nicotine,* *10 mg per cigarette for carbon monoxide'*.[87]
Article 10 – '*Regulation of tobacco product disclosures*'[88] *'Each Party shall […] adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products'*.[89]	Article 6 of the 2001 Tobacco Products Directive '*Member States shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type'*.[90]
Article 11 – '*Packaging and labelling of tobacco products*'[91] '*Each Party shall […] adopt and implement […] effective measures to ensure that: […] (b) each unit packet and package of tobacco products and any outside packaging and labelling […] carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages'*.[92]	Article 5 of the 2001 Tobacco Products Directive '*Each unit packet of tobacco products […] must carry the following warnings: (a) general warnings: 1. "Smoking kills/Smoking can kill," or 2. "Smoking seriously harms you and others around you. […].*'[93]

[85] FCTC, cit., Art. 9.
[86] *ibid.*
[87] 2001 Tobacco Products Directive, cit., Art. 3.
[88] FCTC, cit., Art. 10.
[89] *ibid.*
[90] 2001 Tobacco Products Directive, cit., Art. 6.
[91] FCTC, cit., Art. 11.
[92] FCTC, cit., Art. 11.
[93] 2001 Tobacco Products Directive, cit., Art. 5(2)(a).

Article 13 – '*Tobacco advertising, promotion and sponsorship*'[94]	Article 4 of the Tobacco Advertising Directive
'Each Party shall […] undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship […]'.[95]	*'All forms of radio advertising for tobacco products shall be prohibited'*.[96]

The left column of *Table 1* lists the substantive obligations arising from the FCTC and is limited to provisions for which the EU has the exclusive competence to implement them,[97] while the right column presents examples of how the EU already had the required measures in place prior to the adoption of the FCTC. This overview demonstrates that this selection of newly adopted provisions of the FCTC were already at place in the EU. Similarly, it indicates strong coherence and correlation between the FCTC's provisions and EU tobacco control legislation. In fact, there is direct evidence of the EU's influence on the content of some of the FCTC's norms. The EU acted as a key facilitator for the interpretation of Article 13 FCTC, based its own Tobacco Advertising Directive.[98] This emphasizes the extent to which the EU has 'uploaded' its own normative tobacco control legislation to the WHO-level.

It can be argued that for this reason, namely the reason that its own legislation was 'copied and pasted' into the text of the FCTC, the Union did not have to implement the novel rules of international health law anymore.[99] In fact, however, analysing the further development of the normative content of the FCTC after adoption uncovers relevant insights into how the EU and the WHO continued their multilevel dialogues or, put differently, the constant, continuous process of uploading and downloading.

It must be noted that the dynamic nature of the FCTC plays an important role in this regard. It arises from the fact that the FCTC is a framework convention. Its norms are broadly defined and are subsequently interpreted by the Conference of Parties (COP), so as to determine details at a later point after adoption through protocols and guidelines.[100] The op-

[94] FCTC, cit., Art. 13.
[95] *ibid.*
[96] Tobacco Advertising Directive, cit., Art. 4.
[97] For instance, the *'Protection from exposure to tobacco smoke'*, as required under Article 8 FCTC is not included, as it concerns the regulation of, among other places, indoor workplaces and public places. Similarly, Article 12 FCTC imposes Parties with obligations concerning *'Education, communication, training and public awareness'*. Both obligations are substantive, but do not fall within the EU's competences. Therefore, they are irrelevant for inclusion in Table 1.
[98] *Conference of the Parties to the WHO Framework Convention on Tobacco Control, First Session* (2006) COP/1/2006/CD, ANNEX 4.
[99] EMMERLING, cit., 132.
[100] For an interesting insight into the relevance of framework conventions, although in a different context, please consult NIKOGOSIAN Haik, KICKBUSCH Ilona, *A treaty would protect lives, livelihoods, security and human rights*, BMJ (2021) editorial; NIKOGOSIAN Haik, KICKBUSCH Ilona, *A pandemic treaty: wehre are we now that the leaders have spoken?* BMJ Opinion 2021, available at https://blogs.bmj.com/bmj/2021/04/26/a-pandemic-treaty-where-are-we-now-that-the-leaders-have-spoken/ (consulted 28 June 2021).

portunity for such succeeding interpretation of norms enables the instrument to continuously adjust to changing circumstances. This has led to the fact that novel technical developments or critiques that did not exist yet or were not pertinent during the drafting and adoption of the FCTC can still be addressed by the Convention. The following case studies discuss such instances, namely the regulation of novel tobacco products and the measurement methods of tar, nicotine and carbon monoxide emissions levels.

1. Case Study 1: The regulation of novel tobacco products

A key example in the multilevel dialogue between the EU and WHO concerns the regulation of novel tobacco products, such as e-cigarettes and in particular heated tobacco products (HTPs). These products were only marketed after the negotiations of the FCTC had finished.[101] Accordingly, there was no mention of them in the FCTC: they were not included within the definition of tobacco products,[102] and there was no substantive provision explicitly referring to them. Implicitly, though, their development can be read into Article 22 FCTC.[103] This provision concerns cooperation in the scientific, technical and legal fields and provision of related expertise, and can be interpreted to address scientific and technical developments expanding the scope or applicability of the FCTC progressively. [104]

The problem in this particular case, however, is that the application of existing legislation to these novel products may not be effective, as they distinguish themselves from tobacco products in both their definition and the kind of challenges they pose.[105] Due to, for instance, claims that these products are smoke-free,[106] they can circumvent the application of existing bans and regulations. Similarly, there is debate as to their harmfulness: some argue that they can serve as a gateway to smoking, thereby normalizing tobacco consumption (i.e. when non-smokers start consuming novel products and as a consequence initiate the use of conventional tobacco products),[107] while others submit that they can act as a safer alternative to conventional tobacco products (i.e. smokers cede to smoke conventional cigarettes, but still meet their nicotine needs by smoking novel products).[108] As a consequence, a lack of clarity exists as to how these products should be regulated.[109]

[101] OLIVER Kevin, *Regulations Are a Drag: The WHO Framework Convention on Tobacco Control and Its Potential Application to Electronic Cigarettes*, Chicago Journal of International Law (2015) pp. 185-214, p. 205.
[102] 'Tobacco Products' are defined in the FCTC as 'products entirely or partly made of the leaf tobacco as a raw material which are manufactured to be used for smoking, sucking, chewing or snuffing', FCTC, cit., Art. 1(f).
[103] Oliver, cit. 194, 209.
[104] FCTC, cit., Art. 22; Oliver, cit., 209.
[105] *Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products* [2021] COM(2021) 249 final (hereinafter Report on the TPD), para. 7.
[106] *Our smoke-free products* Philip Morris International, available at https://www.pmi.com/smoke-free-products (consulted 10 January 2022).
[107] GRUSZCZYNSKI Lukasz, MELILLO Margherita, *The FCTC dilemma on heated tobacco products* (2020) Globalization and Health pp. 1-14, p. 3, 10.
[108] *ibid*, p., 10.
[109] Report on the TPD, cit., para. 7.

These issues were coined at the international level in 2008 and have been repeatedly discussed thereafter.[110] The EU was similarly struck by the novel regulatory difficulties.[111] In 2014, the EU decided to adopt early legislation in this field by including the regulation of novel tobacco products in the TPD, namely in Articles 19 and 20.[112] It did so by not extending the application of conventional tobacco control measures, but by developing a hybrid or customized form of regulation. For instance, the TPD imposes stricter obligations with regard to the marketing of e-cigarettes (e.g. notification obligations under Article 19 TPD), while being more lenient with regard to other obligations (e.g. health warnings under Article 20(4)(b)(iii))).[113] These regulatory experiences then served as input for the development of new FCTC guidance on the regulation of novel tobacco products.[114] In 2018, the EU coined a mandate on the topic of novel tobacco products at the 8th COP meeting.[115] In the recent evaluation report of the TPD by the Commission, it emphasized the importance of the lasting dialogue between the WHO and EU with regard to novel tobacco products by stating: *'[t]o […] address the regulatory challenges posed by these products, the EU* initiated *and supported a mandate at the WHO FCTC COP8*'.[116]

The process can be schematically presented in the following manner:

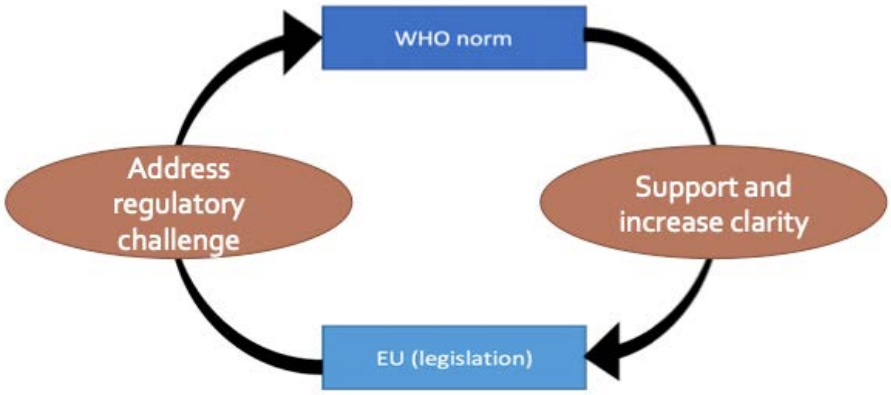

Figure 2. The uploading and downloading of norms between the EU and the WHO in light of the regulation of novel tobacco products.

This case study thus emphasizes and demonstrates how the EU contributes to and influences what is on the agenda at the WHO-level. The Union communicates with the existing channels at the WHO when new developments emerge for which conclusive strategies are

[110] *Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS)* (2018) FCTC/COP/8/10, paras. 1-11.
[111] Report on the TPD, cit., para. 7.
[112] Tobacco Products Directive, cit., Arts. 19-20.
[113] Note how Article 20(4)(b)(iii) requires packaging of e-cigarettes and refill containers to carry health warnings, such as *'This product contains nicotine which is a highly addictive substance'*, as compared to *'Smoking kills'* on the packaging of conventional tobacco products, Tobacco Products Directive, cit., Art. 9(1), Art. 20(4)(b)(iii); GRUSZCZNSKI, MELILLO, cit., p. 10.
[114] *Work in progress in relation to Articles 9 and 10 of the WHO FCTC* (2014) FCTC/COP/6/14 para. 25 and Annex 1.
[115] Report on the TPD, cit., para. 7.
[116] Emphasis added, Report on the TPD, cit., para. 7.

yet to be established, while the WHO relies on the EU's regulatory challenges and experiences in creating guidelines and support. Thereby, both the EU and WHO further their policies: in the case of novel tobacco products, the EU brought the topic to the table and provided input, while the WHO gave the EU support and increased clarity on the difficulties faced.

2. Case Study 2: The ISO method for measuring tar, nicotine and carbon monoxide levels

The consideration of a further example allows for relevant insights on how three relevant levels (i.e. the domestic-, European- and international levels) interact with each other.[117] Article 9 FCTC requires the regulation of the contents and emissions of tobacco products.[118] This had already been regulated under Article 3 of the 2001 Tobacco Products Directive and the measurement standard had been clarified in Article 4 thereof. Here, the EU adhered to the methods for measurement used by the International Organization for Standardization (ISO). During the first COP in 2006, it was decided that Article 9 required further Guidelines to ensure the correct implementation of that provision. With the objective of '*[providing] guidelines for testing and measuring the contents and emissions of tobacco products*',[119] key facilitators were mandated to draft guidelines as to the correct measurement of tobacco emissions and contents.[120] For these particular guidelines, the key facilitators were Canada, the European Community and Norway.[121]

Unsurprisingly, the Guidelines developed after the first COP put forward the ISO standards as the recommended measurement method for tobacco emissions and contents.[122] This is notable, especially given the fact that up to date serious technical discussions exist on what exactly is an adequate measurement method, and both the ISO method and the Health Canada Intense (HCI) are regarded as authoritative methods.[123] In combination with the EU serving as a key facilitator, it is plausible that the use of this standard may have emanated from the EU's tobacco control legislation. The recommendation of the ISO methods in the Article 9 FCTC Guidelines may thus be regarded as a policy 'upload' by the EU to the FCTC-level. Reversely, the Commission recently relied on the international standard: in the ongoing discussions concerning the most adequate measurement method

[117] As indicated in the introduction, the scope of this paper is confined to EU efforts to influence international health law adopted under the auspices of the WHO directly. In this case study, the role of Member States is included and this falls inside the scope of this paper, due to the fact that it concerns the influence of the Member State on the EU, and not on the WHO.
[118] FCTC, cit., Art. 9.
[119] FCTC COP 1, cit., Annex 2.
[120] *ibid.*
[121] *ibid.*
[122] *Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation of the contents of tobacco products and Regulation of tobacco products disclosures)*, FCTC/COP4(1).
[123] Report on the TPD, cit., para. 3, footnote 20. On the implications of these standards, please consult HAMMOND D and others, *Revising the machine smoking regime for cigarette emissions: implications for tobacco control policy* (2007) Tobacco control http://dx.doi.org/10.1136/tc.2005.015297 pp. 8-14.

that similarly exist at the EU-level, the EU argued to be '*[integrating the] standards agreed by the FCTC or by the WHO into EU law*'.[124] Thus, here the Commission submits that this is a 'download' of WHO standards into EU law.

The dialogue on an adequate measurement method does not finish here. In fact, it has been notably extended recently and turned into a 'trialogue'. In March 2020, the validity of the ISO method prescribed by Article 4(1) of the current TPD has been challenged before a domestic court, in the Netherlands.[125] Along the lines of the discussion briefly introduced above, the claimant argued that testing machines utilized for the ISO testing method fail to accurately demonstrate the levels of tar, nicotine and carbon monoxide that consumers inhale in reality.[126] This is caused by the fact that tobacco producers have inserted perforations in the filters of tobacco products, which are blocked by smokers' lips and fingers during the consumption of the products, but allow for additional ventilation when the ISO measuring method is executed.[127] In contrast to this practice, the HCI method covers these perforations in the testing stage. Accordingly, this leads to the fact that the ISO testing method reports the emissions of harmful substances that are two to twenty-six times lower than when the perforations are shut off using the HCI measuring method.[128]

The claimant argued before the Dutch court, among other things, that the content of Article 3(1) TPD is determined by the flawed ISO measurement methods as stipulated in Article 4(1) TPD.[129] Due to the allegedly flawed measurement method prescribed under Article 4(1) TPD, abidance with Article 3 TPD was argued to be at risk, as cigarettes that pass the test do not necessarily comply with the standards stipulated in that provision.[130] Accordingly, the Court communicated a preliminary ruling to the CJEU, asking whether Article 4(1) TPD is in conflict with, among other standards, the object and purpose of the TPD and the FCTC, given the fact that the ISO method does not measure the real emissions smokers are exposed to during consumption.[131]

This question is yet to be answered by the ECJ.[132] The Opinion of Advocate-General (AG) Saugmandsgaard Øe has been published recently, but did not take into consideration the

[124] Report on the TPD, cit., para. 3.1.
[125] Tobacco Products Directive, cit., Art. 4; RBROT, NL:RBROT:2020:2382, para. 6.2.
[126] ibid.
[127] ibid. para. 6.2; SONG Min-Ae and others, *Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma* (2017) Journal of the International Cancer Institute pp. 1-18.
[128] RBROT, cit. para. 6.2; *RIVM meet veel hogere warden van teer, nicotine en koolmonoxide in sigaretten* (2018), available at https://www.rivm.nl/nieuws/rivm-meet-veel-hogere-waarden-van-teer-nicotine-en-koolmonoxide-in-sigaretten (consulted on 5 October 2021).
[129] RBROT, cit., para. 6.1.
[130] ibid, para. 6.2.
[131] ibid, para. 12, vraag 3b. Interestingly, note how the potential provisions with which Article 4(1) TPD is in conflict with are Article 114(3) TFEU and Articles 24 and 35 of the Charter of Fundamental Rights of the European Union, Arts. 24 and 35 Charter of Fundamental Rights of the European Union.
[132] InfoCuria reports that the case is still in progress: C-160/20 – *Stichting Rookpreventie Jeugd and Others*, InfoCuria Case-law, available at https://curia.europa.eu/juris/liste.jsf?lgrec=fr&td=%3BALL&language=en&num=C-160/20&jur=C (consulted 19 January 2022).

relevant question mentioned above.[133] Nevertheless, in its recent evaluation of the TPD, the Commission has alluded to the discussion concerning the disputability of the current prescribed measuring method. In its defence, it relied on the FCTC standards and the recent discussions it is involved in at the FCTC's forum.[134] Accordingly, due to the adherence of the FCTC to the ISO method and due to the lack of a more accurate alternative, the Commission concluded that no revision of the prescribed ISO method in the TPD was necessary.[135]

This case study accentuates that the multilevel dialogues are important for the interpretation of norms that takes place between and at multiple levels, and it emphasizes the interrelatedness of the different levels. Additionally, it stresses the fact that *Figure 1* above is merely a small part of a larger picture: below the box 'EU legislation' belongs another cycle of 'downloading' and 'uploading' processes between the Union and its Member States, as traditionally presented in the literature on Europeanization.[136] The full picture, as illustrated by this case study should thus resemble this figure:

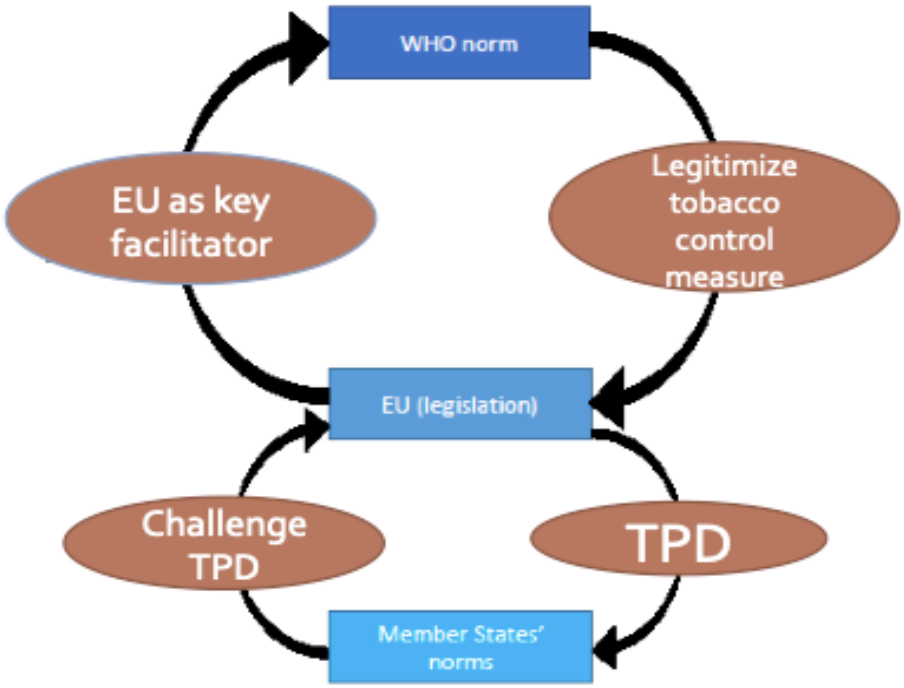

Figure 2. The uploading and downloading of norms between the EU and the WHO in light of the measurement method for tar, nicotine and carbon monoxide levels in tobacco products.

[133] Opinion of AG Saugmandsgaard Øe, Case C-160/20, EU:C:2021:618. Rather, AG Saugmandsgaard Øe primarily took into account the question of whether an externally determined standard (i.e. by the ISO) that is relied on should be accessible free of charge for Union citizens.
[134] Report on the TPD, cit., para. 3.1.
[135] *ibid.*
[136] Note that this cycle between the EU and its Member States has been presented in multiple sources, and has been schematically displayed in, for instance, PRØITZ, cit., p. 72.

The cycle of multilevel dialogue concerning measurement standards commenced with the EU that uploaded its own legislation to the WHO-level during the drafting and subsequent interpretation of Article 9 FCTC. Once the European regulatory measure was challenged, namely when the (public) debate stirred up, the EU relied on the internationally agreed standard at the FCTC's forum. By doing so, it downloaded the WHO's norm in a certain fashion. Given the fact that the Court has not responded to the preliminary ruling yet and that, therefore, there is no conclusive answer as to the technical parts of the issue, it is to be seen how the EU and WHO will continue this ever progressing dialogue.

IV. Concluding remarks

The above analysis has aimed to elaborate on how the EU can influence the content of international health law developed under the auspices of the WHO. It was submitted that due to the limited legal capacities and competences of the EU, both at the WHO and internally in the policy area of health, there is a limited legal space for the EU to exert its influence. Under the constitutional framework of the WHO it only has capacity to potentially become a Party to conventions or agreements, and its accession to WHO Regulations is precluded altogether. Similarly, following the *ERTA*-doctrine, the EU can only engage in external health relations to a limited extent. Article 168 TFEU enables the Union to adopt health measures with limited scopes (e.g. encouraging cooperation), whereas it can only adopt measures with a secondary health element under Article 114 TFEU, which is a legal basis for EU measures furthering the internal market. This translates to limited external health competences: the contents of the international norms must fall within the scopes of Article 168 and 114 TFEU.

Despite these limitations imposed upon formal EU-WHO (law-developing) relations, the EU has proven to be influential at the WHO. When it is not included in processes, its interests are protected through coordinated positions of the Member States, the entities that actually compose the EU. Additionally, the EU has exerted its influences directly in several ways once it was involved in the norm-making processes at the WHO. Two case studies of the EU's role in the development of (certain parts of) the FCTC revealed the significant extent to which the EU has contributed to the current normative content of the international tobacco control regime. These efforts are best characterized by 'multilevel normative processes' and were explained by norm-'uploading' and -'downloading', originating from studies on Europeanization. Particularly Case Study 2 on measurement methods of tobacco product emissions emphasized the degree of influence the EU was able to exert on the interpretation of the relevant FCTC provision. This revealed the 'uploading' process. However, when this uploaded norm was challenged internally, the EU relied on the FCTC standards, thereby 'downloading' the norm again.

The foregoing analysis reveals interesting insights into the EU's role in the development of international health law under the auspices of the WHO. Importantly, the prominence of the two-way, multilevel normative dialogue should not be underestimated. As demonstrated in the case studies, it became obvious that the EU did not only ensure that WHO norms would be compatible with its own legislation (i.e. not only to protect its own interests), but similarly contributed to the further development of norms in general, thereby benefiting both the international and European understanding of health norms. Accordingly, this emphasizes the importance of international cooperation and norm-development between different levels of policy-making. Even if the EU has limited competences, its touch on international health law has promoted the advancement of health standards globally, through international health law – by doing so, the EU can extend its (substantive) influence on health within and beyond its own border.

* * *

List of abbreviations

AG	Advocate-General
COP	Conference of the Parties
ECJ	European Court of Justice
EU	European Union
FCTC	WHO Framework Convention on Tobacco Control
HCI	Health Canada Intense
HTD	Health Threats Decision
IHR	International Health Regulations
ISO	International Organization for Standardization
NCD	Non-communicable disease
REIO	Regional Economic Integration Organization
TPD	Tobacco Products Directive
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization

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