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7 | Legislative standards as part of international health law

7.1 IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS

7.1.1 General

The international spread of disease has been a concern for the international community since 1851, as was discussed in Part I. The International Health Regulations (IHR), which are central to the present section, reflect only the most recent version of international cooperation on the subject. They were adopted in 2005 to replace their predecessor, the 1969 International Health Regulations, which had been amended in 1973 (to add provisions for cholera) and in 1981 (to exclude smallpox from the regulations' scope).⁶¹³ In 1995 a process of revision was set in motion, which has resulted in a new set of rules that entered into force in 2007.⁶¹⁴ One important innovation was that, contrary to their predecessors, the new regulations are not limited to certain specified diseases, such as yellow fever or plague; instead, they apply to any 'illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans'.⁶¹⁵

7.1.2 Content of the Regulations

The new regulations' aim is 'to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade'.⁶¹⁶ In order to achieve that aim, the IHR contain various obligations concerning national and international surveillance, public health response, health measures applied to international travelers, aircraft, ships, motor vehicles and goods, and public health at international ports, airports and ground crossings.⁶¹⁷

613 WHO, 'Revision of the International Health Regulations. Report by the Secretariat' (24 March 2003) A 56/25, 1.

614 WHA res 58.3 (n 278).

615 Art 1, first paragraph.

616 Art 2 IHR.

617 WHO, 'International Health Regulations (2005). A brief introduction to implementation in national legislation' (World Health Organisation, Geneva 2009) WHO/HSE/IHR/2009.2, 2 <http://www.who.int/ihr/Intro_legislative_implementation.pdf> (accessed 29 March 2018).

The main obligations can be summarised as follows. Pursuant to article 4, first paragraph, IHR, states shall designate or establish 'National IHR Focal Points' and the authorities responsible for the implementation of health measures under the regulations. They have a central role in communicating with the WHO and with other domestic authorities.⁶¹⁸ For example, they serve as a channel of communications in case of an event unfolding on a state's territory which may constitute a 'public health emergency of international concern'. States are under an obligation to report such an event to the WHO within 24 hours and to provide all relevant public health information. Subsequently the collected information will be forwarded by the WHO in order to enable other states to respond to the established public health risk.⁶¹⁹ In addition, states have a duty to develop, strengthen and maintain the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern.⁶²⁰ In the event of such an emergency, the Director-General of the WHO temporarily has the power to issue recommendations, which may include health measures regarding persons, baggage, cargo, containers, conveyances, goods and parcels in order to prevent or reduce the international spread of disease.⁶²¹

Furthermore, the IHR impose several obligations regarding the so-called 'points of entry', a term that encompasses airports, ports and ground crossings. The requirements include the duty to identify the competent authorities and the duty to ensure the development of various 'capacities' at designated points of entry, such as the availability of medical staff in order to assess ill travelers and facilities to treat contaminated baggage and cargo etc.⁶²²

The IHR also stipulate that state authorities may on arrival and departure impose requirements for public health purposes with regard to travelers, such as information on the person's itinerary or a medical examination, and inspection of baggage, cargo etc.⁶²³ Similarly, states shall take all practicable measures to ensure that conveyance operators comply with the health measures recommended by the WHO and may take action if a conveyance is suspected to contain sources of infection or contamination.⁶²⁴ Under certain conditions, a state may require invasive medical examination or vaccination, for instance when it is necessary to determine whether a public health risk exists or as a condition for travelers seeking temporary or permanent residence.⁶²⁵

While the aforementioned measures primarily seek to combat established or suspected public health risks, the aim of the IHR is also to diminish unnecessary impediments to international traffic and trade. This follows

618 Art 4, first and second paragraph.

619 Artt 6, first paragraph, 7 and 11.

620 Art 13, first paragraph, and Annex I.

621 Art 15, first and second paragraph.

622 Artt 19, sub a and b, 20 and 21, and Annex I, sub B.

623 Art 23, first paragraph.

624 Art 24, first paragraph, sub a, and 27, first paragraph.

625 Art 31, first and second paragraph.

from various provisions, such as the prohibition of the application of health measures to conveyances in transit not coming from affected areas, and the prohibition to require other health documents than those provided for in the IHR.⁶²⁶

7.1.3 Legislative standards

7.1.3.1 Implementation and harmonisation

The 'Toolkit for implementation in national legislation' acknowledges that implementation of the IHR on the domestic level can be performed in various ways. It reveals, however, a preference for implementation through legislation since, it is submitted, 'there needs to be an adequate legal framework to support and enable all these activities [required by the IHR] within all States Parties'.⁶²⁷ Implementation through legislation is desirable, it is stated, not only since it 'facilitate[s] performance of IHR activities in a more efficient, effective or otherwise beneficial manner', but also because legislation may serve to 'institutionalize and strengthen the role of IHR capacities within the State Party'. An additional potential benefit may be found in enhanced 'coordination among different governmental and non-governmental entities involved in implementation [...]'.⁶²⁸ This preference for implementation through legislative means can be satisfied in two ways, it is argued: legislation that gives effect to the various requirements in each relevant area; or legislation which incorporates the IHR as a whole in the domestic legal system, either by attaching the text of the IHR as an annex or by reference.⁶²⁹

The IHR harmonise national attitudes towards public health responses to the international spread of disease. However, states are expressly permitted to adopt 'additional health measures' in response to specific public health risks or public health emergencies of international concern (both terms are defined in article 1, first paragraph, IHR) which achieve the same or greater level of health protection than recommendations issued by the WHO, or which are otherwise prohibited under several provisions of the IHR. Such additional measures should be otherwise consistent with the IHR and should not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives.⁶³⁰ Put simply, states are allowed to restrict international traffic further if it is

626 Artt 25, 26 and 35. Also artt 33, 40 and 41.

627 WHO, 'International Health Regulations (2005). Toolkit for implementation in national legislation. Questions and answers, legislative reference and assessment tool and examples of national legislation' (World Health Organisation, Geneva 2009) WHO/HSE/IHR/2009.3, 9 <http://www.who.int/ihr/Toolkit_Legislative_Implementation.pdf?ua=1> (accessed 29 March 2018).

628 Ibid.

629 Ibid, 11. The second way is usually called ad hoc statutory incorporation. See section 2.4.

630 Art 43, first paragraph.

necessary in order to respond to an imminent and serious threat to public health. In the same vein, states are free to conclude additional treaties with other states in order to 'facilitate the application of the IHR'.⁶³¹ This means that the IHR does not impose one uniform framework to be applied by states in the context of the international spread of disease; it leaves some discretion to states, although the manner in which states could use this discretion is governed by the IHR.

7.1.3.2 *Observance of human rights, including non-discrimination*

One of the legislative standards that may be derived from the IHR can be found in the provision which calls upon Member states to implement fully the IHR in accordance with the principles embodied in article 3.⁶³² These include the principle that the implementation of the IHR shall be 'with full respect for the dignity, human rights and fundamental freedoms of persons'. Closely related to the implementation of the IHR themselves is the adoption of health measures pursuant to the IHR. They must be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.⁶³³ Pursuant to article 32, health measures pertaining to travelers must be performed 'with respect [for travelers'] dignity, human rights and fundamental freedoms', while minimizing 'discomfort and distress associated with such measures'. To this end, states have a duty to treat all travelers with courtesy and respect, to take into consideration their gender and their sociocultural, ethnic or religious concerns, and to provide those who are quarantined, isolated or subjected to medical examination with adequate food, water, accommodation etc.⁶³⁴

7.1.3.3 *Observance of applicable international and national law*

The drafters of the IHR have intended to ensure that the IHR do not contravene other international legal obligations to which the state parties are bound. On a general level, it is stated that implementation shall 'be guided by the Charter of the United Nations and the Constitution of the World Health Organisation' and 'by the goal of their universal application for the protection of all people of the world from the international spread of disease'.⁶³⁵ Nevertheless, acknowledging the possibility that tension arises between these internationalist objectives and the reality within the jurisdiction of states, the IHR also stipulate that 'states have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of

631 Art 57, second paragraph.

632 WHA res 58.3 (n 278).

633 Art 42.

634 Art 32, sub a, b and c.

635 Art 3, first, second, and third paragraph, IHR.

their health policies. In doing so they should uphold the purpose of these Regulations'.⁶³⁶

Other references to international law can be found in article 57, first paragraph, which stipulates that 'the [IHR] and other relevant international agreements should be interpreted so as to be compatible' and that the rights and obligations derived from those agreements shall not be affected by the IHR. This is not to say that other state obligations than those included in the IHR, will always prevail; it merely states that they should be reconciled, *by means of interpretation*, to the largest possible extent. Whenever a state party is bound by a legal obligation that clearly contravenes the duties set forth in the IHR, interpretation in accordance with article 57, first paragraph, will prove to be insufficient to solve the contradiction. Moreover, in article 46 express reference is made to 'international guidelines' that should be taken into account by states to facilitate the performance various activities with biological substances, diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes.

In several places the IHR refer to national law as well. First of all, the terms 'temporary residence' and 'permanent residence' have the meaning given to them in domestic law.⁶³⁷ Article 45, first and second paragraphs, governs the treatment of personal data that have been collected or received in accordance with the IHR. Such data should be kept confidential and be anonymously processed 'as required by national law'. Thus, the drafters of the IHR have decided to rely on national law for the specification of the cited terms and for norms pertaining to the processing of personal data, instead of integrating the said terms and norms in the IHR.

7.1.4 Overview

From the overview presented in the previous sections, it must be concluded that the legislative standards pertaining to the implementation of the IHR are scarce. The IHR impose various obligations on states that require implementing measures, and, as we have seen, preferably implementing *legislation*, but they do not elaborate on the means and methods of implementing legislation. For instance, the IHR are silent on monitoring and enforcement measures. Nevertheless, on a few occasions they refer to human rights, including non-discrimination, international law and domestic law. These references are not only relevant for the interpretation of the IHR themselves, but also for the interpretation of domestic implementing legislation that is adopted to give effect to the IHR.

636 Art 3, fourth paragraph, IHR. Similarly, it is stated: 'How the IHR requirements are to be implemented is up to each State Party in light of its own domestic legal and governance systems, socio-political contexts and policies. Each State Party should therefore determine the extent to which the different aspects of this guidance may be relevant or appropriate to their particular circumstances. WHO, 'A brief introduction to implementation' (n 617) 7.

637 Art 1, first paragraph.

7.2 IMPLEMENTATION OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL

7.2.1 General

Together with the IHR, probably the best known instrument of international health law may be found in the Framework Convention on Tobacco Control (FCTC). Similar to the IHR, the FCTC was negotiated and adopted under the auspices of the WHO. The FCTC was adopted in 2003 by the World Health Assembly in accordance with article 19 of the Constitution of the WHO, which bestows it with the power to adopt international conventions.⁶³⁸ It is the product of a process that commenced in 1970 with the adoption of a resolution on the serious health effects of smoking.⁶³⁹ In May 1995 this process resulted in the adoption by the Health Assembly of a resolution in which the Director-General was requested to investigate the feasibility to develop an international instrument on tobacco control.⁶⁴⁰ In 1999 it was decided that an intergovernmental negotiating body should formulate a draft text of the treaty.⁶⁴¹ After the adoption of the text of the treaty in May 2003, it was opened for signature in June 2003 and entered into force in February 2005. The FCTC is a 'framework convention' and may be complemented by protocols in accordance with article 33. This has resulted in the adoption of the Protocol to Eliminate Illicit Trade in Tobacco Products in November 2012.⁶⁴² Today 181 states are bound by the FCTC; 31 states are party to the Protocol.⁶⁴³

638 WHO (Resolution of the World Health Assembly), 'WHO Framework Convention on Tobacco Control' (21 May 2003) WHA56.1. Article 19 of the Constitution of the WHO, stipulates: 'The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organisation. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes'.

639 WHO (Resolution of the World Health Assembly), 'Health consequences of smoking' (19 May 1970) WHA 23.32.

640 WHO (Resolution of the World Health Assembly), 'An international strategy for tobacco control' (12 May 1995) WHA 48.11.

641 WHO (Resolution of the World Health Assembly), 'Towards a WHO framework convention on tobacco control' (24 May 1999) WHA 52.18.

642 Conference of the Parties to the WHO Framework Convention on Tobacco Control, 'Protocol to Eliminate Illicit Traffic in Tobacco Products' Decision FCTC/COP5(1) (12 November 2012) <[http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5\(1\)-en.pdf](http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5(1)-en.pdf)> (accessed 29 March 2018).

643 See the FCTC website: http://www.who.int/fctc/signatories_parties/en/ and <http://www.who.int/fctc/protocol/en/> (accessed 29 March 2018).

7.2.2 Content of the Convention

The objective of the FCTC is to ‘protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures [...]’.⁶⁴⁴ In order to achieve this objective, the FCTC prescribes various measures. The FCTC distinguishes between general obligations, which are entrenched in article 5 FCTC, and other obligations.

The general obligations include the duty to ‘adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke’.⁶⁴⁵ Furthermore, states have a duty to protect their public health policies with respect to tobacco control from undue influence of the tobacco industry and to cooperate with each other and with other competent international bodies.⁶⁴⁶ In addition to article 5, the FCTC prescribes the adoption of measures aimed at the reduction of demand for tobacco, the protection from exposure to tobacco smoke, the reduction of the supply of tobacco, the protection of the environment, liability, and scientific and technical cooperation.⁶⁴⁷ Examples include the consideration of price and tax measures in order to discourage the use of tobacco products, the adoption and implementation of effective measures providing for protection from exposure to tobacco smoke in indoor workplaces and public places, the adoption and implementation of measures to ensure that tobacco packages and labels contain health warnings describing the harmful effects of tobacco use, the adoption and implementation of measures aimed at strengthening public awareness on the health effects of tobacco use, the adoption and implementation of measures that prohibit the sale of tobacco products to minors, and the development and promotion of national research programmes relating to tobacco control.⁶⁴⁸

Furthermore, the FCTC provides for the establishment of a Conference of the Parties, which ‘shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation’.⁶⁴⁹

644 Art 3.

645 Art 5, second paragraph, sub b.

646 Art 5, third, fourth and fifth, paragraph.

647 Parts III, IV, V, and VI.

648 Artt 6, 8, second paragraph, 11, first paragraph, 12, 16, first paragraph, and 20, first paragraph.

649 Art 23, first and fifth paragraph.

7.2.3 Legislative standards

7.2.3.1 Implementation, 'guiding principles' and harmonisation

The central obligation of the FCTC can be found in article 3, which states that the treaty provides for a framework for tobacco control measures 'to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke'.

When states adopt the national measures required by the FCTC, they should take into account, it is stipulated, *inter alia*, the 'guiding principles' set out in article 4. These principles stress the need for information to the public on the health effects which result from the use of tobacco products, the need for 'strong political commitment' and international cooperation, the importance of 'comprehensive multisectoral measures and responses to prevent health damage', of issues of liability, and of 'technical and financial assistance to aid the economic transition of tobacco growers and workers', and the essential role of civil society in the attainment of the FCTC's objectives. These principles may be viewed as a brief summary of the FCTC and may contribute to the understanding, for the purposes of interpretation, of the treaty text in accordance with article 31, first paragraph, VCLT. This provision stipulates that the interpretation of treaties should not only be conducted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context, but also 'in the light of its object and purpose'.⁶⁵⁰

Notwithstanding their importance as a means of interpretation, the guiding principles laid down in article 4 probably do not constitute autonomous legal obligations to be performed by the state parties, as their legal substance can only be established in connection with the other FCTC provisions.

In this context it is worth referring to the *Guidelines for implementation*, which have been drafted and elaborated over the years in order to promote the implementation of the FCTC.⁶⁵¹ These guidelines reflect 'the consolidated views of parties on different aspects of implementation, their experiences and achievements, and the challenges faced'.⁶⁵² Instead of focusing on the implementation of the FCTC in its entirety, it elaborates on the implementation of specified articles such as article 8 on the protection from the exposure to tobacco smoke.⁶⁵³ The Guidelines should probably be character-

⁶⁵⁰ VCLT art 31, first paragraph.

⁶⁵¹ WHO, *Guidelines for implementation* (n 177). As an additional tool to enhance compliance with the Convention, the Convention Secretariat annually publishes 'Global Progress Reports' on the implementation of the Convention <http://www.who.int/fctc/reporting/summary_analysis/en/> (accessed 29 March 2018).

⁶⁵² WHO, *Guidelines for implementation* (n 177) v.

⁶⁵³ Other provisions to which the Guidelines apply, are articles 5, third paragraph, 9, 10, 11, 12, 13 and 14.

used as a soft law instrument, which may be derived from the statement that 'Parties are encouraged to use these guidelines not only to fulfill their legal duties under the Convention, but also to follow best practices in protecting public health'.⁶⁵⁴ To this end, the Guidelines on article 8 FCTC provide for seven 'principles' that should guide the implementation of article 8, and clarify various aspects of the implementation, such its scope, enforcement, monitoring and evaluation.⁶⁵⁵

Finally, the FCTC contains minimum standards. This may be derived from article 2, first paragraph, which encourages state parties to 'implement measures beyond those required by this Convention [...]', adding that 'nothing in these instruments shall prevent a Party from imposing stricter requirements'.⁶⁵⁶

7.2.3.2 Observance of applicable international and national law

Several provisions of the FCTC refer to international and national law, which indicates that implementation should be performed in a manner that is consistent with other legal norms to which the state is bound. As was noted above, the state parties to the FCTC may adopt stricter requirements than the requirements prescribed by the FCTC in order to better protect human health. However, there are two conditions that have to be met: those additional measures must be consistent with the provisions of the FCTC and with international law in general.⁶⁵⁷ Similarly, the FCTC expressly stipulates that state parties have the right to conclude bilateral and multilateral agreements, provided that those agreements are compatible with the obligations under the FCTC. In short, the FCTC requires what may be termed consistency with other international legal provisions. This requirement may seem, at first sight, unnecessary, since it is nothing more than an affirmation of the obvious principle that states should act in accordance with the obligations to which they are bound: *pacta sunt servanda*. However, it may be understood to point to a certain hierarchy, which ensures the prevalence of the FCTC over other applicable international agreements or domestic laws. Which international legal norms the drafters had in mind remains unclear, unfortunately, since the FCTC and the *Guidelines for Implementation* are silent on this topic.

654 WHO, *Guidelines for implementation* (n 177) 19.

655 Principle 4, for example, provides that '[g]ood planning and adequate resources are essential for successful implementation and enforcement of smoke free legislation'. WHO, *Guidelines for implementation* (n 177) 21-29.

656 Art 2, first paragraph. See also article 13, fifth paragraph.

657 Art 2, first paragraph.

In addition to the references to international law, the FCTC on several occasions points to national law.⁶⁵⁸ In these cases, the FCTC does not impose one single, harmonised norm to be followed by all state parties; instead, it allows some level of discretion to national authorities that are responsible for the implementation of the relevant provision. An example may clarify this point. Article 13, fourth paragraph, sub a, provides:

'[...] in accordance with its constitution or constitutional principles, each Party shall: (a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions';

In the *Guidelines for Implementation*, relating to this particular provision, it is accepted that domestic law may provide for limitations on the imposition of a ban on tobacco advertising. Given these limitations, it is submitted, the state in question should apply restrictions on tobacco advertising which are 'as comprehensive as possible in the light of those [limitations]'.⁶⁵⁹ In this particular aspect, thus, the FCTC provision may not be interpreted as to prevail over domestic (constitutional) laws applicable to tobacco advertising.

In other FCTC articles, references to domestic laws ensure the complementary, instead of restrictive, character of those laws. This is the case in article 16, first paragraph, which stipulates:

'Each Party shall adopt and implement effective legislative, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or eighteen'.

Here, the legal regime pertaining to the sale of tobacco products to minors that is entrenched in the FCTC relies on domestic law for the purpose of setting an age limit; only if such domestic laws are absent, the FCTC sets the age limit on eighteen years. Admittedly, the characterisation of references to national law in the text of the FCTC as 'restrictive' or 'complementary' is in essence a matter of perspective; in principle, any such reference may be viewed as both restrictive and complementary at the same time. Whereas a preference for a qualification as restrictive may reveal support for the protection of state sovereignty, the labeling as 'complementary' points to an internationalist approach in which states take common action to solve common problems. In the end, the key issue is that the references to national law which are part of the FCTC, indicate that the FCTC on the one hand and the domestic laws of a state party on the other, are *connected*. In those cases, as a consequence, it is imperative to take into account both sides in order to identify the applicable law.

658 For instance, articles 5, third paragraph, 6, second paragraph, 10, 11, first paragraph, 13, 14, first paragraph, 16, first paragraph, 19, third paragraph, 20, fourth paragraph.

659 WHO, *Guidelines for implementation* (n 177) 103.

7.2.3.3 Compliance and enforcement

Moreover, the implementation of the FCTC entails the obligation to put in place a compliance and enforcement mechanism in order to ensure compliance with the specified FCTC articles. It must be emphasised that the FCTC does not contain any obligation to this effect that is applicable to the treaty as a whole. Rather, it must be derived from specified treaty articles or, in the absence thereof, from the *Guidelines for Implementation*. Pursuant to the *Guidelines for Implementation* compliance with article 8 should be monitored, which requires the establishment of inspection procedures. These procedures may, it is added, be integrated into existing health and sanitation inspections, inspections for workplace health and safety or fire safety inspections.⁶⁶⁰ As regards articles 9 and 10 FCTC on the regulation of the content of tobacco products, including the publication of information about their content, the *Guidelines for Implementation* stipulate that domestic implementing measures 'should identify the authority or authorities responsible for enforcement, and should include a system both for monitoring compliance and for prosecuting violators'.⁶⁶¹ The *Guidelines for Implementation* proceed to describe in detail the features of this compliance mechanism, such as the availability of a budget, information to stakeholders and the recommendation to use inspectors and enforcement agents to conduct regular visits to manufacturing facilities to verify whether any prohibited ingredient is being used.⁶⁶² State authorities should have the authority to seize, forfeit and destroy any tobacco products that do not meet the requirements of the articles 9 and 10.⁶⁶³

Other enforcement measures may be required under on article 5, third paragraph, FCTC, which codifies the duty of states to protect their public health policies from the commercial interests of the tobacco industry.⁶⁶⁴ The obligation to provide for an enforcement mechanism includes the possibility for the imposition of penalties for violations of the FCTC. Again, the FCTC does not contain a general obligation to this effect. Therefore, it must be partly derived from two specified articles, which provide for the obligations to '[...] enact or strengthen legislation, *with appropriate penalties and remedies*, against illicit trade in tobacco products, including counterfeit and contraband cigarettes' and to '[...] adopt and implement effective legislative, executive, administrative or other measures, *including penalties* against sellers and distributors, in order to ensure compliance with the obligations contained in [article 16, paragraphs 1 to 5]'.⁶⁶⁵

660 Ibid, 26.

661 Ibid, 45. The Guidelines contain an identical statement with regard to article 8 of the Convention. Ibid, 26.

662 Ibid, 45-46.

663 Ibid, 47.

664 Ibid, 12.

665 Artt 15, fourth paragraph, sub b, and 16, sixth paragraph. Italics added.

Although the 2013 edition of the *Guidelines for Implementation* do not elaborate on the requirement of penalisation as referred to in articles 15 and 16, it does imply the need for, and the duty to impose, penalties for transgressions of *other* provisions of the FCTC. This is remarkable, because the latter FCTC provisions do not contain an obligation to this effect. Here the *Guidelines for Implementation* clearly go beyond what could be derived from the text of the treaty itself. According to the *Guidelines for Implementation* regarding article 11, '[p]arties should specify a range of fines or other penalties commensurate with the severity of the violation [...]'.⁶⁶⁶ Similarly, states should 'introduce and apply effective, proportionate and dissuasive penalties' in response to violations of the prohibition of, or restrictions applicable to, tobacco advertising, as embodied in article 13.⁶⁶⁷ The penalties may encompass fines, corrective advertising remedies and licence suspension or cancellation.⁶⁶⁸ With respect to the aforementioned articles 9 and 10, the *Guidelines for Implementation* prescribe that '[p]arties should specify appropriate sanctions, such as criminal sanctions, monetary amounts, corrective actions, and the suspension, limitation or cancellation of business and import licences'.⁶⁶⁹

7.2.3.4 Participation of stakeholders

In addition, the FCTC and its supporting documents envisage the involvement of stakeholders in the implementation of measures to attain the formulated policy aims. The most important stakeholders include a wide range of organisations or groups, businesses, restaurant and hospitality associations, employer groups, trade unions, the media, health professionals, organisations representing children and young people, institutions of learning or faith, the research community and the general public.⁶⁷⁰

The involvement of stakeholders which are part of civil society may be based partly on the guiding principle entrenched in article 4, seventh paragraph, already discussed above, which emphasises the participation of civil society in order to achieve the objective of the FCTC. To this end, it is recommended that states 'work with civil society to create a climate of attitude that [...] identifies legislative priorities and helps develop and enforce

⁶⁶⁶ Ibid, 66.

⁶⁶⁷ The emphasis on deterrence also becomes visible in relation to article 8. In the *Guidelines for Implementation*, it is noted that 'penalties should be sufficiently large to deter violations or else they may be ignored by violators or treated as mere costs of doing business'. Ibid, 25.

⁶⁶⁸ Ibid, 110-111.

⁶⁶⁹ Ibid, 46.

⁶⁷⁰ Ibid, 24. A distinction must be made between the tobacco industry and other stakeholders. As regard the former, states should take into account in article 5, third paragraph, which provides that national public health policies regarding the use of tobacco product should be protected from commercial or other interests of the tobacco industry.

legislative measures'.⁶⁷¹ Elsewhere it is noted that 'broad consultation with stakeholders is also essential to educate and mobilize the community and to facilitate support for legislation after its enactment'.⁶⁷²

Also after its entry into force, contacts with stakeholders are believed to enhance compliance with domestic implementing measures. In the context of article 8 FCTC on protective measures against the harmful effects of tobacco smoke, the *Guidelines for Implementation* provide that:

'[o]nce legislation is adopted, there should be an education campaign leading up to implementation of the law, the provision of information for business owners and building managers outlining the law and their responsibilities and the production of resources, such as signage. These measures will increase the likelihood of smooth implementation and high levels of voluntary compliance. Messages to empower non-smokers and to thank smokers for complying with the law will promote public involvement in enforcement and smooth implementation.'⁶⁷³

7.2.3.5 Monitoring and evaluation of measures

After domestic implementing measures have been adopted, the question arises whether those measures should be monitored and, if yes, how. Under several FCTC obligations, the need for monitoring and evaluation of measures is emphasised. Their exact purpose, as formulated in the *Guidelines for Implementation*, varies from article to article. In relation to article 8, for instance, it is noted that the monitoring and evaluation of measures to reduce tobacco smoke serve multiple aims, such as the increase of public and political support for strengthening and extending legislative provisions and to shed light on efforts made by the tobacco industry to undermine implementation measures.⁶⁷⁴ Under article 11, on packaging and labeling of tobacco products, the objective of monitoring and evaluation seems to be broader, namely to assess the impact and possible improvement of the adopted measures.⁶⁷⁵ Similarly, the monitoring and evaluation of the laws adopted under article 12 on education, communication, training and public awareness regarding tobacco control issues, allows states to 'measure progress' and to 'identify best practices'.⁶⁷⁶ A purpose that is connected to monitoring and evaluation and which is common to all of the aforementioned provisions, is the assistance of states, that will benefit from the experiences of other states.⁶⁷⁷

671 Ibid, 83.

672 Ibid, 24.

673 Ibid.

674 Ibid, 28.

675 Ibid, 67.

676 Ibid, 86.

677 Ibid, 28, 67 and 86.

7.2.4 Overview

In view of the above, several conclusions may be drawn in relation to the implementation regime that has been established under the FCTC. In order to promote the implementation of the FCTC, the Conference of the Parties have drafted *Guidelines for Implementation* which clarify and elaborate the obligations to which states are bound under the treaty. Their legal status is such that they probably do not constitute binding obligations supplementary to the FCTC text. Nevertheless, the fact remains that the guidelines go beyond what is required under the text of the treaty. They refer to the need for inspection and enforcement procedures under several FCTC provisions, whereas those provisions do not stipulate such obligation. The formulation of standards on the consultation with stakeholders and on the evaluation of domestic implementing measures is quite rare in international legal practice. In addition to these standards for legislation, it is clear that the drafters have intended to embed the FCTC, and the required domestic implementing laws, within the existing international and national legal framework.