

## TOBACCO PRODUCTION AND TRADE IN MACEDONIA – THE LEGAL FRAMEWORK AND POLICY IN LIGHT OF ACCESS TO THE EU AND THE GLOBAL MARKETS\*

*Abstract: In the paper the author analyses the national legislation related to the production (manufacture) and trade (sale) of tobacco and tobacco products. The aim of the research is to establish the level of the harmonization of the national legislation to the relevant EU and international instruments in the field. The paper examines the specific rules for agricultural production of tobacco and its treatment as controlled substance, from the aspect of administrative prerequisites and contractual relations that emerge. The key issue of interest is the regulation of the standards and conditions for releasing the tobacco and tobacco products on the markets, with emphasis on the labelling requirements. Beside these issues, the author also deals with the other policy instruments related to the tobacco control. It is concluded that the current legislation is not aligned with the applicable EU law in this field and that further legislative activities are needed. The author stresses that political will be needed not only to enact new legislation but also to effectively and efficiently enforce it.*

*Key words: Tobacco, – Tobacco products, – Tobacco Products Directive, – Framework Convention on Tobacco Control.*

### 1. INTRODUCTION

If the decision on allowing sale tobacco products was made today, most probably it would have been outlawed. The position of the World Health Organization (WHO) is that "Tobacco is the only legal drug that kills many of its users when used exactly as the manufacturers intended"<sup>1</sup>, with annual death toll of over 7 million persons each year<sup>2</sup>. The position of the European Union is similar, insisting

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1 WHO global report: mortality attributable to tobacco, 2012, p. 4 ([http://apps.who.int/iris/bitstream/10665/44815/1/9789241564434\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44815/1/9789241564434_eng.pdf); last access 28.01.2018)

2 WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. p.2. [http://apps.who.int/iris/bitstream/10665/258874/1/9789241512824\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/258874/1/9789241512824_eng.pdf?ua=1); last access 31.01.2018.

on measures that will decrease the smoking rates, for the wellbeing of the people, but also for economic benefit, as "A reduction in tobacco consumption of just 2% translates into annual healthcare savings of approximately €506 million for the EU."<sup>3</sup> The instruments on tobacco control aim at reducing the demand and supply of tobacco products. The WHO Framework Convention on Tobacco Control (FCTC) is the pre-eminent global tobacco control instrument that provides for comprehensive direction for tobacco control policy at all levels. Its provisions are binding on the Union and its Member States. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences. The EU finds that the FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant, and requires harmonized approach lack of a harmonised approach to regulating the ingredients of tobacco products. It is found that its lack affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. It is expected that without harmonisation, the obstacles to the smooth functioning of the internal market will increase in the coming years, taking into account the implementation of the FCTC and the relevant FCTC guidelines throughout the Union and in the light of experience gained in other jurisdictions outside the Union<sup>4</sup>. This is one of key reasons the European Union adopted the new Tobacco Products Directive in 2014, repealing Directive 2001/37/EC<sup>5</sup>.

What is the position of the Republic of Macedonia in these global and EU developments? On 30<sup>th</sup> of June 2016, it acceded to the FCTC thus become obliged to develop and enforce its tobacco control policies in line with the Convention. In regard to the implementation of the EU standards in tobacco control, such obligation arises from the Stabilisation and Association Agreement (SAA)<sup>6</sup> signed on 9 April 2001 in Luxembourg<sup>7</sup>. The SAA in Art. 68, obliges Macedonia on approximation of the

3 Statement of Commissioner Vytenis Andriukaitis, STATEMENT/16/1882, [[http://europa.eu/rapid/press-release\\_STATEMENT-16-1882\\_en.htm](http://europa.eu/rapid/press-release_STATEMENT-16-1882_en.htm)]; last access 31.01.2018).

4 Recitals (15), 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; *OJ L 127, 29.4.2014, p. 1–38*; hereinafter Tobacco Products Directive 2014.

5 Directive 2001/37/EC of the European Parliament and of the Council 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; *OJ L 194, 18.7.2001, p. 26–35*; hereinafter Tobacco Products Directive 2001.

6 Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Macedonia, of the other part – Protocol 1 on textile and clothing products – Protocol 2 on steel products – Protocol 3 on trade between the Republic of Macedonia and the Community in processed agricultural products – Protocol 4 concerning the definition of the concept of "originating products" and methods of administrative cooperation – Protocol 5 on mutual administrative assistance in customs matters – Final Act; *OJ L 84, 20.3.2004, p. 13–197*.

7 The formal process of initiating negotiations about the EU's Stabilisation and Association Process started in 2000. The Stabilisation and Association Agreement (SAA) was signed on 9 April 2001 in Luxembourg. It was ratified by the Macedonian parliament on 12 April 2001, and was the first to be ratified by all the member states and came into force on 1 April 2004.

existing and future laws to those of the Community, thus Macedonia shall endeavour to ensure that its laws are gradually made compatible with those of the Community. The tobacco and related tobacco products as processed agricultural product, pursuant to Art. 25 of the SAA, are subject to duties as provided in the Protocol 3 to the SAA. As per Annex I, for tobacco and related products originating in the Republic of Macedonia duties are set to zero for imports into the Community, while for the good originating in the community on imports in the Republic of Macedonia the duty is 70% of the MFN (as of 2003 onwards). The export of the tobacco is high on the list of the exported products and the value gradually increases over the years. Thus, if in 2015 it was 10,2 million EUR, in 2016 it increased to approximately 12,1 million EUR, while in 2017 the value reached over 18 million EUR. Still it has not reach its pick of over 21 million in 2013. However, the past year we were faced with a deficit in the trade – the value of the imported tobacco goods compared to the exported increases as well (over 29 million EUR in 2017). The tobacco and tobacco products are mostly exported in the EU and the CEFTA countries<sup>8</sup>. The accession to the Central European Free Trade Agreement also obliges the Republic of Macedonia to *expand trade in goods and services and foster investment by means of fair, clear, stable and predictable rules* (Art. 1/2/c of CEFTA) and the tobacco and tobacco products are under the regime of agricultural products (Art. 9 – 11).

The status of the legislation and the policies, however, is not affected only by these obligations. In the development of the policy instruments the status of the tobacco agricultural production and the manufacture i.e. the tobacco industry in the national economy should be taken into consideration. Namely, as per the available data approximately 30% of the state budget is provided from revenues of the tobacco industry. In 2017, it is so far reported that approx. 16.000 tons of tobacco have been bought-out on average price of 207 Denars<sup>9</sup> per kilogram i.e. for total price of 3,337,973,508.81 Denars<sup>10</sup>. In addition, the state provided subventions in the amount of 60 Denars<sup>11</sup> per kilogram.

The Law on Tobacco and Tobacco Products<sup>12</sup> is the general act that regulates the primary production (production) and the financing, buy-out, storage, processing of the purchased raw tobacco in leaf (tobacco<sup>13</sup>), the trade with processed tobacco, as well as the production and trade of tobacco products<sup>14</sup>. Its current version

8 CEFTA Trade Statistics 2015 [<http://cefta.int/wp-content/uploads/2016/05/CEFTA-Trade-Statistics-Brochure-2015.pdf>]; CEFTA Trade Statistics 2016 (FIRST HALF) [[http://cefta.int/wp-content/uploads/2016/05/CEFTA\\_Trade-Statistic-Borchre-2016\\_1H.pdf](http://cefta.int/wp-content/uploads/2016/05/CEFTA_Trade-Statistic-Borchre-2016_1H.pdf)]

9 This equals to approximately 3,36 EUR (as per the average rate of the National Bank of the Republic of Macedonia (NBRM)).

10 This equals to approximately 54.260.111 EUR (as per the average rate of the NBRM).

11 This equals to approximately 0,975 EUR (as per the average rate of the NBRM).

12 Law on Tobacco and Tobacco Products ("Official Gazette of the Republic of Macedonia" nos. 24/2006, 88/2008, 31/2010, 36/2011, 53/2011, 93/2013, 99/2013, 164/2013, 151/2014, 193/2015, 213/2015 and 39/2016); hereinafter LTTP.

13 Tobacco, in terms of this Law, shall be the leaves obtained from the plant species of *Nicotiana tabacum* L. (Art. 2, LTTP).

14 Tobacco products are products made of tobacco intended for smoking, chewing and sniffing (Art. 3/1/2, LTTP). The following shall be considered tobacco products: 1) cigars and cigarillo, 2) cigarettes, and 3) smoking tobacco. (Art. 4/1, LTTP). This definition is in line with Art.



has been enacted in 2006 and subsequently amended several times. When the Law was enacted, as stated in the explanatory note to the proposal, the proposer (the Government of the Republic of Macedonia) had in mind the provisions of the FCTC and the Tobacco Products Directive 2001. Its legislative development did not reflect the changes that were happening in the regulation of the tobacco production and products in the EU. Namely, most of them were enacted aiming at vertical harmonization with other relevant laws in the administrative field. On the positive note, as we were informed by the Ministry of Agriculture, Forestry and Water Resources Management, a new law is in its final stage of development. The Tobacco Control Directive 2014 and the latest developments under the FCTC are fully taken into consideration and integrated in the text. What is to be expected is included in this analysis from the point of the European legislation development.

## 2. THE LEGAL REGIME OF TOBACCO PRODUCTION

The issue of the tobacco production is not within the scope of the WHO and the EU instruments. The national legislator opted for a model of controlled production, so as to control the amounts of the substance on the market. The limitations that exist are in several aspects related to the parties who can participate in the process, the manner in which the production process is carried out, the reporting obligations towards the relevant ministry.

### 2.1. General condition for production

Under the LTTP (Art 6) tobacco may be produced by family agricultural holdings and legal entities (producers) on the basis of a contract for tobacco production and buy-out concluded with a legal entity registered for tobacco buy-out and processing (buyer). The LTTP regulates in detail the conditions and the procedure for trade companies, whose main activity is wholesale of raw tobacco, to be recorded in the register of tobacco buyers kept by the Ministry of Agriculture, Forestry and Water Resources Management.<sup>15</sup>

The LTTP obliges the producer before the conclusion of the contract to report the tobacco production to the Ministry of Agriculture, Forestry and Water Resources Management<sup>16</sup>. The Ministry issues record detailing the reported production from all cadastral parcels where tobacco is to be produced, per type and amount of tobacco to the holder of the agricultural holding. The possession of this record is precondition for the conclusion of the contract, as each concluded contract is regis-

<sup>15</sup> 1/1 of FCTC that defines that "tobacco products" mean products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing, as well as Art. 2/1 of Tobacco Products Directive where "tobacco products" means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not.

<sup>16</sup> Art. 20 - 22a, LTTP.

<sup>17</sup> The deadline for reporting for a given production year, until March 31 in the current year at the latest. The reporting is in the regional branch office of the Ministry, where the head office or the place of residence of the producer is located, regardless of the place of performance of the agricultural activity (Art 7/1, LTTP).

tered in the record sheet<sup>17</sup>. These data are kept in the Single Register of Agricultural Holdings<sup>18</sup>. The reporting obligation is imposed to the buyer as well. Namely, the tobacco buyer is to report the agreed tobacco production to the Ministry.<sup>19</sup>

The tobacco producers can produce tobacco using only certified seed material (seed material) from the tobacco buyers. The tobacco buyer, is obliged to provide, free of charge, seed material, according to the agreed acreage, in the quantity of at least 90 g/ha for oriental tobacco, 40 g/ha for semi-oriental tobacco and 20 g/ha for large leaves types of tobacco, and for pelleted seed in the quantity of at least 250 g/ha for oriental tobacco, 90 g/ha for semi-oriental tobacco and 40 g/ha for large leaves types of tobacco. In addition, the tobacco buyer is obliged to provide products for protection of the plants<sup>20</sup>.

All of the tobacco that has been produced the tobacco producer is selling to the to the buyer with whom the contract has been concluded under the agreed conditions. An exception to this exists only in the cases when the parties terminate the contract under the conditions determined by the LTTP<sup>21</sup>.

#### 2.1. Contractual relations between the producer and the buyer

For the purpose of tobacco production, the producer concludes a contract for tobacco production and buyout (contract) with a tobacco buyer. The LTTP, limits the producer for one production year and one same production, for a defined quantity, to conclude a contract with only one buyer<sup>22</sup>.

The LTTP regulates, in too many details, the form of the contract, the deadline for its conclusion and its basic elements.

Thus, in accordance with Art. 12, LTTP contract is concluded in a written form. As per the general rules of the Law on Obligations, the lack of such form will lead to invalidity of the contract<sup>23</sup> It must be concluded, until April 10<sup>th</sup> at the latest for the current year<sup>24</sup>. Following this deadline, as per Art. 12/8, a contract may be

<sup>17</sup> Art. 12/6, LTTP.

<sup>18</sup> The form and content of the record sheet, the necessary documents and the manner of issuance of the record sheet are prescribed by the Ministry of Agriculture, Forestry and Water Resources Management. The Ministry, also, establishes an electronic system for keeping the records of reported, registered, and agreed areas and quantities of tobacco per producers, buyers, per tobacco types, for each harvest separately (Art. 7/3 and Art. 7/6, LTTP).

<sup>19</sup> In accordance with Art. 9, LTTP, the tobacco buyer each production year, until May 30, reports in written or electronic form the agreed tobacco production for the current harvest to the regional branch office of the Ministry of Agriculture, Forestry and Water Resources Management. The buyer is also obliged to enter the data on the agreed tobacco in the electronic system of the Ministry. The with Rulebook prescribes the manner of registration, the form and the content of the registration form for the agreed tobacco production and keeps records on the agreed tobacco production, for the current harvest.

<sup>20</sup> Art. 8, LTTP.

<sup>21</sup> Art. 10, LTTP.

<sup>22</sup> Art. 11/3 and Art. 12/3, LTTP.

<sup>23</sup> Art. 59/1 in relation with Art. 62/1 of the Law on Obligations („Official Gazette of the Republic of Macedonia no. 18/2001, 4/2002, 5/2003, 84/2008, 81/2009, 161/2009 and 123/2013); hereinafter LOO.

<sup>24</sup> Art. 12/7, LTTP.



concluded with a producer, if the buyer with whom a contract has been concluded is under bankruptcy or liquidation or is deleted from the registry of tobacco buyers.

Beside defining the contents of the contract, the LTTP stipulates that contents of the contract, are subject to an opinion from the highest association of tobacco producers<sup>25</sup>.

In regard to the elements, the LTTP provides that in particular contains: the contracting parties; the subject of the contract (acreage, cadastre parcels, type<sup>26</sup> and sort); purchase price of the tobacco by classes; duration of the contract; rights and obligations of the contracting parties; compensation for the representative of the association of tobacco producers for the organization and representation during the buy-out; manner of, and time period for payment of the purchased tobacco; provisions for unilateral termination of the contract; provisions for transfer of the contract; time and place of concluding the contract; advance payment and manner of advance payment, and protection of the tobacco seedling and the tobacco on the field from diseases and pests.

The LTTP further provides for specific provisions on certain elements of the contract.

Regarding the duration of the contract, the LTTP (Art. 15) defines that the concluded for the annual harvest, and can be concluded for more production years. If the later is a case, the right, the obligations and other issues for each production year shall be regulated with an annex to the contract for the production year. This is particularly relevant for the buy-out price as it varies each year based on the market conditions.

In general, the LTTP defines (Art. 17) that the contract terminates: – upon the fulfilment; – upon the expiry of the time period concluded thereof; – by a mutual consent of the contracting parties; – upon a unilateral termination, and – by force of law. The unilateral termination of the contract is not precisely defined by the Law. On one hand side the LTTP provides that both parties have the right to unilaterally terminate the contract, under the conditions and manner set by the contract. On the other the Law seems to limit the unilateral termination of the contract by the producer, stipulating in Art. 18/2 that the *producer shall have the right to terminate the contract if the buyer has an open bankruptcy procedure or is under bankruptcy or is in the process of liquidation or is deleted from the registry of tobacco buyers*. The termination of the contract, in any case, is followed by an administrative procedure for its registration with the relevant Ministry which is noted in the record sheet of the producer. The party sustaining damage from the unilateral termination has the right to compensation in accordance with the general rules regarding damage liability<sup>27</sup>.

The LTTP provides for the opportunity the contract to be transferred to third party and in prescribing the conditions (Art. 16) follows the general rules set by the

<sup>25</sup> As per Art. 12/3, if the highest association of tobacco producers submits a negative opinion about the contents of the contract, the buyer shall be obliged to harmonize the contracts according to the opinion of the highest association of tobacco producers within a period of five days.

<sup>26</sup> As per Art. 12/4, the buyer may conclude one contract with the producer for several types of tobacco.

<sup>27</sup> Art. 19, LTTP and Art. 121/1 LOO.

LOO<sup>28</sup>. Namely, the LTTP requires that the party remaining consents to the transfer in the same (written) form in which the contract is concluded. The transfer of the contract is also reported, but there is no specific provision that should be noted in the record sheet.

In regard to the advance payment, the LTTP in Art. 14 stipulates that it cannot be lower than 15% of the average purchase price for the agreed type established for the previous year. In accordance with Art. 14, the advance payment cannot be lower than 15% of the average purchase price for the agreed type established for the previous year. The other specificities related to the manner of advance payment of the production the parties define by the contract.

### 3. PRODUCTION OF AND TRADE WITH TOBACCO PRODUCTS

The production of tobacco products trade with tobacco products, export and import is exclusively limited to legal entities that are registered in the trade register for performance of the business activity production of tobacco products i.e. for export and import of tobacco products and entered in the register of producers, exporters and importers of tobacco products kept by the relevant Ministry (Ministry of Agriculture, Forestry and Water Resources Management and Ministry of Economy respectively). The requirements for registration both for production of tobacco products<sup>29</sup> and for trade with tobacco products, export and import<sup>30</sup> and for are prescribed by LTTP.

#### 3.1. The 'quality' of the tobacco products

The LTTP precisely and in detail prescribes the standards that must be met in order a tobacco produced to be released on market. Obtaining a certificate for quality and safety is a precondition for the trade, export and import with tobacco products<sup>31</sup>. There is, however certain ambiguity in the LTTP, as when prescribing the procedure for obtaining the certificate it relates it only to the export and the

<sup>28</sup> Art. 132/1, LOO.

<sup>29</sup> As per Art.35/2, LTTP, the legal entities have to meet the following requirements: 1) to have at their disposal installed equipment that enables them to carry out all production phases, from preparation and cutting of the tobacco until production and hygienic packaging of the product; 2) to have at their disposal appropriate laboratory for the purpose of analysis and control of the quality of the tobacco products; 3) to have at their disposal appropriate premises in order to store tobacco and tobacco products, and 4) – to employ at least one person with higher education (agronomist, technologist) in the production process and quality supervision. The specific conditions for the requirements 1) to 3) are in detail prescribed by the Minister of Agriculture with by-law (Art. 35/3).

<sup>30</sup> As per Art. 36/3, LTTP, the legal entities have to meet the following requirements: 1) to have at their disposal appropriate warehousing premises; 2) to have at their disposal appropriate storage equipment, and 3) – to employ at least one person with higher education and at least one year of working experience in tobacco trading. The specific conditions for the requirements 1) and 2) of this Article are prescribed by the Minister of Economy (Art. 36/4).

<sup>31</sup> Art. 36/2, LTTP.



import. Namely, Art. 57 and Art. 58 set the jurisdiction of the State Agricultural Inspectorate to control the quality and safety of the processed tobacco and of the tobacco products during export and import. The quality of the product is determined based on the check of the amount of tar, nicotine and carbon monoxide in the basic smoke of the cigarette by an accredited laboratory<sup>32</sup>. The measured data are compared to the content of tar, nicotine and carbon monoxide in the tobacco products stated on the tobacco products packaging. In determining the content of tar, nicotine and carbon monoxide with cigarettes the internationally recognized and national standards: ISO 4387 for tar content, ISO 3400 and ISO 10315 for nicotine content and ISO 8454 for carbon monoxide content are used.<sup>33</sup> The adequacy of the content of tar, nicotine and carbon monoxide stated on the packaging is confirmed in accordance with the standard ISO 8243.<sup>34</sup> Once the check and verification is completed it is reported to the State Agricultural Inspectorate. This report is the basis for issuing the certificate for quality of the tobacco products.

The LTTP in Art. 40<sup>35</sup> prescribes that tobacco products and smoking tobacco cannot contain any prohibited additives, unknown substances, harmful materials and other pollutants/contaminators (physical, chemical and biological). The additives being allowed to be used in the production of tobacco products and smoking tobacco, their correct purpose of use and the relevant hygiene requirements are prescribed by the Minister of Health on a list of allowed additives<sup>36</sup>. The domestic and imported cigarettes cannot contain additives which are not allowed in the Republic of Macedonia.

The manner of measuring the harmful material and other pollutants/contaminators (physical, chemical and biological), as well as the manner and methods of taking samples for the purpose of determining the harmful material and other pollutants/contaminators (physical, chemical and biological) in the tobacco products is regulated by a by-law enacted by the Minister of Agriculture, Forestry and Water Resources Management in cooperation with the Minister of Health<sup>37</sup>.

The specific amounts of the substances, in their maximum amounts are prescribed by the LTTP. Art. 41 of LTTP, as Art. 3/1 of Tobacco Products Directive 2001, sets that cigarettes that are released into trade cannot contain more than: 10 mg tar/cigarette, 1 mg nicotine/cigarette, and 10 mg carbon monoxide/cigarette. These limits, however, do not apply to production of cigarettes intended for export

<sup>32</sup> Art. 58/3, LTTP in line with Art. 4/2 of Tobacco Products Directive 2001.

<sup>33</sup> Art. 58/5, LTTP in line with Art. 4/1/1<sup>st</sup> sentence of Tobacco Products Directive 2001.

<sup>34</sup> Art. 58/6, LTTP in line with Art. 4/1/2<sup>nd</sup> sentence of Tobacco Products Directive 2001.

<sup>35</sup> In line with Art. 12 and Art. 13 of Tobacco Products Directive 2001.

<sup>36</sup> List of Prohibited Additives (Official Gazette of the Republic of Macedonia No. 56/2007 and 61/2007) and List of List of Prohibited Additives (Official Gazette of the Republic of Macedonia No. 56/2007). As per Art. 40/4, upon a request of the Ministry of Health the producers and importers of tobacco products shall be obliged to submit on a prescribed form data about the additives which are used during the production of the tobacco products and smoking tobacco.

<sup>37</sup> Rulebook on the manner of carrying out control of the quality and the safety of measuring the ingredients, form, content and manner of issuing certificate and methods for taking samples for the analysis of the quality of tobacco products (Official Gazette of the Republic of Macedonia" No. 42/2012).

into countries where this prohibition does not exist. This exclusion is not explicitly provided in the Tobacco Products Directive 2001. Recital 11 provides that this Directive has consequences for tobacco products which are exported from the European Community, as the export regime is part of the common commercial policy. Health requirements, pursuant to Article 152(1) of the Treaty and the case law of the Court of Justice of the European Communities, form a constituent part of the Community's other policies. Thus, rules should be adopted in order to ensure that the internal market provisions are not undermined. Recital 17, in the same time provides that the application of tar, nicotine and carbon monoxide ceilings to exported cigarettes should be subject to transitional arrangements in order to allow more time to change product specifications and to allow for the establishment of internationally agreed standards.

### 3.2. Labelling of tobacco products

The Tobacco Products Directive 2001<sup>38</sup> gives a priority to the health protection in the context of harmfulness of the tobacco<sup>39</sup>. This is also one of the most prominent reason for the adoption of the FCTC. Both instruments set a number of rules on the labelling of the tobacco products intended to the consumers' information but also with aiming at dissuading the consumers to the use products. These requirements are fully effected into the national legislation.

In accordance with Art. 42 of the LTTP release into trade of cigarettes whose packaging does not contain the data regarding the content of tar, nicotine and carbon monoxide in milligrams per cigarette<sup>40</sup> is prohibited. The data have to be imprinted on the side of the packaging and cover at least 10% of the imprinted side, and at least 12 % of the imprinted side if another language is used besides the Macedonian<sup>41</sup>.

The packaging of tobacco products and each external packing, with an exception of transparent packaging and transport boxes, that are released into trade, as per Art. 43<sup>42</sup>, must have the following information imprinted:

- 1) name of the tobacco product;
- 2) description of the tobacco product: cigarette, cigar, cigarillos, pipe tobacco, cigarettes tobacco, chewing tobacco and sniffing tobacco;
- 3) name of the producer and the importers that enables identification and an address;
- 4) number of units (cigarettes, cigars, cigarillos) or weight (consumption tobacco, for sniffing, chewing tobacco);
- 5) in the case of cigarettes, quantity values of tar, nicotine and carbon monoxide in the basic smoke, as following: - 'tar X mg/cigarette' (where X is a round whole number); 'nicotine Y mg/cigarette' (where Y is a number

<sup>38</sup> As stated it is being taken as point of reference for the Macedonian legislation.

<sup>39</sup> Recital 4, Tobacco Products Directive 2001.

<sup>40</sup> As anticipated in Art. 41/1, LTTP.

<sup>41</sup> Art. 41/2, LTTP in line with Art. 5/1-3 of Tobacco Products Directive 2001.

<sup>42</sup> The labelling obligations are set in Art. 11/1/b and Art.12 of FCTC.



- rounded on first decimal point), and 'carbon monoxide Z mg/ cigarette' (where Z is a round whole number);
- 6) serial number or equivalent that enables the determination of the place and date of production of the tobacco product, and
  - 7) warning regarding health (with an exception to the snuff and the chewing tobacco)<sup>43</sup>.

The information required to be provided, exception of information on name and serial number (points 1 and 6), besides in Macedonian language and its Cyrillic letters can be also written in another language spoken by at least 20% of the citizens and its letters, depending on the producers and the importers opinion.

The general warning shall have to cover at least 30% including the frame on the front side, and the additional warning at least 40% including the frame on the back side on the appropriate area of the single packaging of the tobacco product wherein imprinted. In cases when the information are written in another language besides the Macedonian, the general warning shall have to cover at least 32% including the frame on the front side, and the additional warning at least 45% of the back side on the appropriate area of the single packaging of the tobacco product wherein imprinted<sup>44</sup>.

The application of the general and the additional warning shall have to be alternate (rotatory) in a manner guarantying regular presence of all warnings, that is to enable each warning to appear equally on the produced quantities.

The packaging of tobacco products, with an exception of the cigarettes, whose best visible area is greater than 65 cm<sup>2</sup>, as per Art. 44<sup>45</sup>, must contain the warning covering at least 22.5 cm<sup>2</sup> of the area on the front and 22.5 cm<sup>2</sup> of the area on the back side of the packaging. In cases when another language besides Macedonian is used, the warnings should cover least 24 cm<sup>2</sup> of the area of the front and 24 cm<sup>2</sup> of the area of the back side of the packaging.

The legislation, as per Art. 5/6 of Tobacco Products Directive 2001, in Art. 43 of LTTP defines the manner in which the warnings have to be imprinted, specifying that this should be done: 1) with bolded, small (except the first letter of the warning and wherever needed due to relevant grammatical rules) black letters, font Helvetica on a white surface; 2) on part of the packaging not being intended for opening or

<sup>43</sup> a) general warning (on the front side): smoking kills/ smoking can kill or smoking is harmful to you and others around you; b) additional warning (on the back side): smokers die younger; smoking causes heart diseases and heart attack; smoking causes lung cancer; smoking during pregnancy can harm your baby; protect the children, do not let them inhale smoke; your doctor can help you quit smoking; smoking is an addiction disease; by quitting smoking you will reduce the risk of serious diseases; smoking can cause slow and painful death; ask for help to quit smoking; smoking can reduce blood flow and cause impotence; smoking can cause skin aging; smoking can reduce fertility; and cigarette smoke contains gas, nitrosamine, formaldehyde and hydrogen cyanide; and c) additional picture warning (on the back side) clearly representing the harmful effect of the smoking, printed over one of the messages referred to in subpoint b). The pictures about the harmful effects of the tobacco are prescribed by the Minister of Health with a Rulebook ("Official Gazette of the Republic of Macedonia" no. 94/2009.

<sup>44</sup> In line with Art. 5/5 of Tobacco Products Directive 2001.

<sup>45</sup> In line with Art. 5/4 of Tobacco Products Directive 2001.

throwing during the package opening; 3) in the middle of the area where the text is to be printed, where it should be parallel to the edge of the top of each packaging, and 4) so that it is not possible to remove or destroy, nor be hidden by darkening or covering using other inscriptions or symbols.

The size of the letters of each warning of the tobacco products packaging and the pictures shall have to be determined in such manner as to cover the surface area to the highest possible extent.<sup>46</sup> LTTP further specifies that texts of the data on the maximum tar, nicotine and carbon monoxide yields and the warnings<sup>47</sup> referred to in of this Law shall have to be framed, wherefore the width of the frame cannot be smaller than 3 mm, nor greater than 4 mm. The warnings, further, cannot be imprinted on the control stamp glued on the tobacco product packaging. Except for cigarette packaging, the warnings can be also imprinted on a sticker, provided that the sticker is irremovable.

The consumers are specifically protected by prohibiting any information that may mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption. Thus, as per Art. 46 of LTTP it is prohibited to insert texts, descriptions or other signs on the tobacco product packaging containing markings, words or phrases referring or suggesting that the particular type is less harmful than others (for example: low tar, light, mild, ultra-light and other similar markings)<sup>48</sup>.

Although the Tobacco Products Directive 2001 in recital 26 foresees that the greatest possible transparency of product information should be ensured, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the tobacco manufacturers the LTTP does not have a specific provision to this regard. The issue of the intellectual property rights is not specifically regulated in FCTC. This instrument, once can say, goes a step further than Tobacco Products Directive 2001, providing that the trademark of the tobacco product also should not directly or indirectly create the false impression that a particular tobacco product is less harmful than other tobacco products.

#### 4. OTHER POLICY MEASURES RELATED TO PRODUCTION AND TRADE

The FCTC in order to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke<sup>49</sup> provides for and requires putting in place a number of tobacco control measures at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke. These measures are aimed to affect the demand as well as the supply. The core demand reduction provisions in the FCTC (Art. 6 to Art. 14) include

<sup>46</sup> As prescribed in Art. 43/3 and 4 and Art. 44 of LTTP for such warnings.

<sup>47</sup> Those of Art. 43/1/7, LTTP.

<sup>48</sup> Recital 27, Tobacco Products Directive 2001: Art. 11/1/a, FCTC.

<sup>49</sup> Art. 3: Objectives, FCTC.



price and tax measures to reduce the demand for tobacco and non-price measures to reduce the demand for tobacco, namely: – protection from exposure to tobacco smoke; – regulation of the contents of tobacco products; – regulation of tobacco product disclosures; – packaging and labelling of tobacco products; – education, communication, training and public awareness; – tobacco advertising, promotion and sponsorship; and – demand reduction measures concerning tobacco dependence and cessation. The core supply reduction provisions in FCTC (Art. 15– Art.17) regulate the illicit trade in tobacco products; sales to and by minors; and provision of support for economically viable alternative activities.

In the national legislation these measures are dispersed in different laws, but for the purpose of this paper we will focus on those most directly related to the supply of products and services.

#### 4.1. Price and tax measures

FCTC in Art. 6, affirms that the Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons. Without prejudice to the sovereign right of the Parties to determine and establish their taxation policies, each Party should take account of its national health objectives concerning tobacco control and adopt or maintain, as appropriate, measures which may include: (a) implementing tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption; and (b) prohibiting or restricting, as appropriate, sales to and/or importations by international travellers of tax- and duty-free tobacco products. It is argued that any attempt by the authorities to maintain a high retail price can be seen as a health promotion initiative<sup>50</sup>.

This is reflected in the national legislation by imposing excise duties on the territory of the Republic of Macedonia paid directly or indirectly on consumption of, *inter alia*, tobacco products<sup>51</sup>. Subject to excise duty on tobacco products<sup>52</sup> are: 1) cigars and cigarillos, 2) cigarettes and 3) smoking tobacco, being: – finely chopped tobacco for wrapping cigarettes and – other tobacco for smoking. As per Art. 42-c of LE, the excise duty on cigars and cigarillos amounts 21,37 Denar<sup>53</sup> a piece and 0% of the retail price; excise on cigarettes amount 1,353 Denar<sup>54</sup> a piece and 9% of the retail price. If the combined excise is under the amount of 1,553 Denar<sup>55</sup> per piece, the minimum excise shall apply to that amount: excise on tobacco for smoking as finely chopped

<sup>50</sup> I. Thygesen, "Is the EU Harmonization of Excise Taxes on Tobacco Products a Barrier to Health Promotion?", 41 *Interfax* 146 (2013), p. 152.

<sup>51</sup> Art. 1, Law on Excise ("Official Gazette of the Republic of Macedonia" nos. 32/2001, 50/2001, 52/2001, 45/2002, 98/2002, 24/2003, 96/2004, 38/2005, 88/2008, 105/2009, 34/2010, 24/2011, 55/2011, 135/2011, 82/2013, 98/2013, 43/2014, 167/2014, 188/2014, 129/2015, 154/2015, 192/2015, 23/2016, 31/2016 and 171/2017); hereinafter LE.

<sup>52</sup> Art. 41/1, LE.

<sup>53</sup> This equals to approximately 0.347 EUR (as per the average rate of the National Bank of the Republic of Macedonia (NBRM)).

<sup>54</sup> This equals to approximately 0.022 EUR (as per the average rate of NBRM).

<sup>55</sup> This equals to approximately 0.025 EUR (as per the average rate of NBRM).

tobacco amount 1.500,00 Denar<sup>56</sup> per kilogram and 0% of the retail price and as other tobacco for smoking amount 1.350,00 Denar<sup>57</sup> per kilogram and 0% of the retail price. The LE provides for gradual increase of the rate of the specific and minimum excise duty on cigars referred<sup>58</sup>. The LE provides that for the purpose of establishing the calculation basis<sup>59</sup>, retail price is the individual price determined by the producer or importer as unit trade price for cigars, cigarillos and cigarettes per piece and for tobacco for smoking per kilogram. If only the price per pack is determined, retail price shall be considered the price deriving from the price per pack and the content of the pack. The calculation of the excise duty on tobacco for smoking is made on the net weight at the moment of excise chargeability. The producer, i.e. the importer also determines the retail price for the goods that are transferred without compensation as well. This price must not be lower than the individual price of the adequate tobacco products. The producer i.e. the importer is obliged to report the retail price of the tobacco products to the Customs Administration and publish it in the "Official Gazette of the Republic of Macedonia" prior to the release of the tobacco products in the free excise-legal circulation at prices determined in such a manner. The provided measures are also aligned th the Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco<sup>60</sup>

The sales of tobacco and tobacco products is subject to payment of the value added tax (VAT)<sup>61</sup> according to the general tax rate of 18%<sup>62</sup>. The special VAT regime imposed on the tobacco and tobacco products is seen in the various provisions that exclude the right to refund the value added tax<sup>63</sup> and non-exemption from paying VAT tax at import of goods<sup>64</sup>.

The WHO estimates that by these taxation measures the taxation share in the price of the cigarettes is 71% and the over financial developments, including the pricing, in the course of the years made them more affordable.<sup>65</sup>

<sup>56</sup> This equals to approximately 24,38 EUR (as per the average rate of NBRM).

<sup>57</sup> This equals to approximately 21,94 EUR (as per the average rate of NBRM).

<sup>58</sup> In accordance with Art. 42-c/5 and 6, as of the 1st of July, 2014 up to the 1st of July, 2015, the rate of the specific and minimum excise duty on cigarettes r shall be increased by 0,15 Denar per piece on the 1st of July every year, while as of the 1st of July, 2016 up to the 1st of July, 2023, the rate of the specific and minimum excise duty on cigarettes shall be increased by 0,20 Denar per piece on the 1st of July every year. In accordance with Art. 42-c/7 as of the 1st of July, 2014 up to the 1st of July, 2023, the amount the excise duty on tobacco for smoking as finely chopped tobacco shall be increased by 50 Denar per kilogram on the 1st of July every year.

<sup>59</sup> Art. 43, LE.

<sup>60</sup> Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco; *OJ L* 176, 5.7.2011, p. 24–36.

<sup>61</sup> Law on Value Added Tax ("Official Gazette of the Republic of Macedonia" nos. 44/1999, 59/1999, 86/1999, 11/2000, 8/2001, 21/2003, 19/2004, 33/2006, 45/2006, 101/2006, 114/2007, 103/2008, 114/2009, 133/2009, 95/2010, 102/2010, 24/2011, 135/2011, 155/2012, 12/2014, 112/2014, 130/2014, 15/2015, 129/2015, 225/2015, 23/2016 and 189/2016); hereinafter LVAT.

<sup>62</sup> Art. 28, LVAT.

<sup>63</sup> Art. 25/2, LVAT.

<sup>64</sup> Art. 27b, LVAT.

<sup>65</sup> WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO, p. 73 [http://apps.who.int/iris/bitstream/10665/255874/1/19789241512824-eng.pdf?ua=1&ua=1; last access 31.01.2018].



## 4.2. Non-price measures

The FCTC provides for several non-price measures to reduce the demand for tobacco, including protection from exposure to tobacco smoke and tobacco advertising, as well as measures to reduce supply including prohibition of sales to and by minors. These issues in the national legislation are part of the subject-matter of the Law on Protection Against Smoking<sup>66</sup>, which regulates the protection against harmful effects of smoking tobacco and other tobacco-based products on the citizens, the environmental protection, the prohibition of smoking in certain public premises, and the prohibition of cigarette advertising.

The *protection from exposure to tobacco smoke* demanded by Art. 8 of the FCTC is based on the recognition by the parties that scientific evidence has unequivocally established that exposure to tobacco smoke causes death, disease and disability. The FCTC establishes that each Party shall adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels the adoption and implementation of effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places. The LPAS stipulates (Art. 3) that as a rule smoking is forbidden in the public premises<sup>67</sup>. By exception, smoking is allowed only outside the business facility (terrace, summer garden and alike) under specific conditions<sup>68</sup>. The responsible person in the legal entity must display a no-smoking sign and provide control over the smoking prohibition in the public premises and the rooms for accommodation of non-smokers in the facilities for guest accommodation.

<sup>66</sup> Law on Protection Against Smoking ("Official Gazette of the Republic of Macedonia" nos. 36/1995, 70/2003, 29/2004, 37/2005, 103/2008, 140/2008, 35/2010, 100/2011 and 157/2013); hereinafter LPAS.

<sup>67</sup> As per Art. 2, LPAS, public premises are: - facilities where educational activities are carried out and facilities for stay and accommodation of children, pupils and students; - facilities of the healthcare and social institutions; - indoor and outdoor premises used for sports events; - indoor premises used for cultural and entertaining events, gatherings and other public performances; - space outside the business facility, intended, designed, and equipped for the purpose of providing catering services, including additional fixtures (roofs, walls, glass, foils, plasticized or nylon barriers, and alike) whereby the space is closed from all sides and becomes an indoor space; - aerial cableways and ski-lifts; - public means for transport of passengers; - facilities where food is produced, prepared, served, sold and consumed and internet cafés; - premises of the state administrative bodies and institutions and in the bodies of the local self-government units used for holding meetings and gatherings; - restaurants, cafeterias, night bars, café bars, cabarets, disco clubs and breweries; - joint premises in a building and joint parts of a building (light houses, elevators, boiling rooms and alike) determined by law, and - other public premises (halls, offices, working premises, waiting lounges, corridors and alike).

<sup>68</sup> The LPAS (Art. 3(1)(2)<sup>st</sup> sentence and Art.3(2) sets that in order smoking to be allowed outside of the premises the space should be covered and opened from at least three sides, and there are no barriers (glass, foils, plasticized or nylon barriers, and alike) or it is an open space not covered with awnings, umbrellas, and alike, being laterally closed (disco clubs in open spaces, terraces, summer gardens, and alike). In the capacities where guests are accommodated, rooms for accommodation of smokers may be determined but up to 30% of the capacity of the facility, at the most.

The detailed regulation of the *prohibition of advertising* of tobacco products and the tobacco industry in Art. 4 of LPAS, meets the minimum requirements set by Art.13/4 of FCTC<sup>69</sup>. The LPAS forbids to advertise tobacco products and tobacco industry in any form, directly or indirectly<sup>70</sup>, externally or internally.<sup>71</sup> The LPAS further defines that tobacco products may be exhibited at the selling points (kiosk, store, restaurant etc.) solely in their original packages including the standard information on the price.

The FCTC in Art. 6, requires each Party to adopt and implement effective legislative, executive, administrative or other measures<sup>72</sup> at the appropriate government level to prohibit the *sales of tobacco products by and to persons under the age set*

<sup>69</sup> As per Art. 13/6, as a minimum, and 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; (b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship; (c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public; (d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited; (e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and (f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

<sup>70</sup> Indirect advertising of tobacco and tobacco-based products with the name of tobacco product, but not being one, is also prohibited. The use of logo, letters, signs, symbols, slogans, place of production which have been used in relation with the tobacco-based products in the past or are being currently used shall be also considered as indirect advertising (Art. 4/4, LPAS).

<sup>71</sup> This includes advertising especially: at public places and public premises; in the daily, weekly and monthly press, as well as in other magazines; at radio and television; by film slides and films; bulletins, boards and stickers; awnings, parasols or umbrellas; any kind of advertising materials able to be exposed in the selling places (change return tray, all kinds of pendants and hangers and alike); at facilities and on/in means of transport (traffic); mega and citylights; on and in books, calendars, clothes and other advertising material and presents; promotional activities: winning games, different kinds of promotions, any form of direct contact and communication with the consumers (internet, SMS, promotions, presents and alike) and sponsorship and donations of sports, cultural, musical, entertaining and other public shows and events by enterprises or other legal entities in the production and sale of tobacco-based products. Public premise, for the purpose of advertising prohibition also include any place available to anybody, with or without entrance ticket: streets, squares, ports, beaches, parks; administrative and business and residential buildings; - sports, recreation, cultural and entertaining facilities; hotel, restaurants and other hospitality facilities; and shopping centers, stores, kiosks and alike.

<sup>72</sup> These measures may include: (a) requiring that all sellers of tobacco products place a clear and prominent indicator inside their point of sale about the prohibition of tobacco sales to minors and, in case of doubt, request that each tobacco purchaser provide appropriate evidence of having reached full legal age; (b) banning the sale of tobacco products in any manner by which they are directly accessible, such as store shelves; (c) prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors; and (d) ensuring that tobacco vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors.



by domestic law, national law or eighteen. In addition, the FCTC demands the distribution of free tobacco products to the public and especially minors to be prohibited or the prohibition to be promoted. Endeavours should also be made to prohibit the sale of cigarettes individually or in small packets which increase the affordability of such products to minors.

The national legislation meets the requirements of the FCTC by prohibiting to sell cigarettes and tobacco to individuals younger than 18 in the retail sale outlets<sup>73</sup>, forbidding the sale of cigarettes in the facilities located in sports and recreational areas<sup>74</sup>, as well as forbidding sale of tobacco products per piece (per cigarette), sale from automates, places of self-service, as well as sale by ordering<sup>75</sup>. As per the requirements of Art. 16/6 of FCTC adopt and implement effective legislative, executive, administrative or other measures, including penalties against sellers and distributors, in order to ensure compliance with the obligations related to minors, the Law foresees a fine in the amount of Euro 2.000 to 4.500 in Denar counter-value for a misdemeanour on the legal entity that acts contrary to these prohibitions.

## 5. THE WAY AHEAD

The implementation of the new standards for tobacco products in the Macedonian legislation is (over)due. The (new) Tobacco Products Directive 2014 was adopted by the Council on 14 March 2014 and entered into force on 19 May 2014. By 20 May 2016 it was transposed by all Member States<sup>76</sup>.

The new directive introduces major novelties intended to further discourage people from smoking or encourage them to quit. In relation to the warning, labelling and packages new sets of detailed rules are introduced.<sup>77</sup> Thus, it is foreseen the health *warnings* to be larger (65% of the pack) and include photos, text and cessation information. Further, the tar, nicotine and carbon monoxide *labelling* tobacco are to be replaced with an information message that informs consumers that 'Tobacco smoke contains over 70 substances known to cause cancer.' Under the new regulations, the *packaging* is standardised in shape and content (no less than 20 cigarettes) and any promotional and/or misleading features or elements on the packages are explicitly forbidden. For the purpose of gathering more information on the ingredients contained in tobacco products and their effects on health and addic-

<sup>73</sup> Art. 5, LPAS.

<sup>74</sup> Art. 5-a/1, LPAS.

<sup>75</sup> Art. 5-a/2, LPAS.

<sup>76</sup> It is to be noted that the new features of the Directive were challenged before the Court of Justice of the European Union. Poland, supported by Romania, challenged the prohibition of menthol cigarettes, and in two other cases the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court) asks the Court of Justice whether a number of provisions of the directive on tobacco products are valid. In the Judgments in Cases C-358/14 Poland v Parliament and Council, C-477/14 Pillbox 38(UK) Limited v Secretary of State for Health and C-547/14 Philip Morris Brands SARL and Others v Secretary of State for Health, the Court found that extensive standardisation of packaging, the future EU-wide prohibition on menthol cigarettes and the special rules for electronic cigarettes are lawful.

<sup>77</sup> Art. 8 – Art. 14, Tobacco Products Directive 2014.

tion *mandatory electronic reporting on ingredients* is introduced for manufacturers and importers of tobacco products<sup>78</sup>. As of May 2020, cigarettes and roll-your-own tobacco with *characterising flavours will be ban*. A procedure for determining whether a tobacco product has a characterising flavour has been established, and an independent advisory panel will be set up to assist the Commission and Member States in this respect<sup>79</sup>. The directive introduces certain safety and quality requirements for *e-cigarettes* containing nicotine, including maximum nicotine concentrations and maximum volumes for cartridges, tanks and nicotine liquid containers; packaging and labelling rules for e-cigarettes; and obligations for monitoring and reporting of developments related to e-cigarettes<sup>80</sup>. The directive provides that the EU Member States may *prohibit cross-border distance sales* of tobacco products, which give consumers access to products that do not comply with the Directive<sup>81</sup>. Last but not the least, the directive introduces specific *measures to combat illicit trade*, which include an EU-wide tracking and tracing system for the legal supply chain and a security feature composed of visible and invisible elements (e.g. holograms) which should help law enforcement bodies, national authorities and consumers detect illicit products. These measures will be introduced for cigarettes and roll-your-own tobacco in 2019 and to tobacco products other than cigarettes and roll-your-own tobacco in 2024<sup>82</sup>.

Having in mind the fact that a new Law on Tobacco and Tobacco Products is being drafted within the Ministry of Agriculture, Forestry and Water Resources Management, it is to be expected that the national legislation will soon put in place the same standards and obligations for the domestic manufacturers and trades as in the European Union. Still, the implementation of these rules in practice, for the benefit of the people and the public health system will depend on the political will and commitment to effectively and efficiently enforce them. Considering that *the policy objective of protecting human life and health is of the utmost importance, while the extent to which compliance can be left to the voluntary discretion of industry is low*<sup>83</sup> it is of utmost importance the state to create environment for strict obedience to the law.

<sup>78</sup> Art. 5, Tobacco Products Directive 2014.

<sup>79</sup> Art. 7, Tobacco Products Directive 2014.

<sup>80</sup> Art. 20, Tobacco Products Directive 2014.

<sup>81</sup> Art. 18, Tobacco Products Directive 2014.

<sup>82</sup> Art. 15 and Art. 16, Tobacco Products Directive 2014.

<sup>83</sup> A. Davies, "Technical Regulations and Standards under the WTO Agreement on Technical Barriers to Trade", *Legal Issues of Econ. Integration* 37 (2014), 45.



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**LEGAL IMPLICATIONS  
OF TRADE LIBERALIZATION  
UNDER SAAs AND CEFTA**

edited by  
**Dušan V. Popović**



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