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EU Competence in the Area  
of Public Health:  
Complementary or Complete?

The Case of Tobacco for Oral Use

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# Summary

This thesis evaluates the EU-level tobacco products regulation and the regulation of tobacco products for oral use, in particular. The evaluation includes a historical overview of the development of relevant secondary legislation and a more detailed analysis of the current regulatory state.

Following the analysis of the Tobacco Products Directive as the main legal instrument in the European tobacco regulation, a more detailed evaluation is made to the suitability of the choice of Article 114 TFEU as the Directive's legal basis. The main issues relating to EU competence in the field of public health are also addressed.

Following the theoretical analysis, the thesis presents the most relevant case law concerning the challenging of the Tobacco Products Directive, and analyses the respective judgments.

Finally, the thesis provides an overview of the potential effects of the currently on-going revision of the Tobacco Products Directive, and examines the potential future development of the European regulation of tobacco products for oral use.

# Preface

My personal interest in the chosen topic arose during a course on the new challenges of the internal market operated by my supervisor Jörgen Hettne. The topic is of great current interest due to the fact that the Tobacco Products Directive, which is at the centre of this thesis, is at the moment going through a revision procedure.

I am very grateful for having had the opportunity to get to know so many wonderful colleagues during the Master's Programme in European Business Law at Lund University. The professional and inspiring study atmosphere created by co-students and university staff has been one of a kind.

Finally, I would like to thank Jörgen Hettne for his helpful and encouraging comments during the process of writing the thesis.

20 May 2012, Helsinki, Finland

*Joonas Oikarinen*

# Abbreviations

AG	Advocate General
CJEU	Court of Justice of the European Union
DG SANCO	Directorate General for Health and Consumers
EC	Treaty Establishing the European Community
EEA	European Economic Area
EEC	Treaty Establishing the European Economic Community
EU	European Union
FCTC	Framework Convention on Tobacco Control
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
WHO	World Health Organisation

# 1 Introduction

The regulation of tobacco products in the EU follows an increasingly harmonised pattern. In general, tobacco products are regulated as to their lawful contents by setting the maximum allowed levels of harmful substances and additives. However, the regulation of specific tobacco products for oral use – moist powder or portion-packed tobacco product, which is placed under the upper lip – differs substantially from that of other tobacco products, including other smokeless tobacco products. Instead of focusing on their lawful contents, the EU legislation extra-ordinarily regulates tobacco products for oral use as to their physical composition and the way in which they are intended to be used.

Since the adoption of secondary legislation in the early 1990s, the Member States are prohibited from placing on the market tobacco products for oral use. The subsequent accession of Sweden to the EU has created a unique *status quo* for tobacco products for oral use. Sweden enjoys a derogation from the prohibition, which results in a complete partitioning of the market for the tobacco products concerned. Naturally, such partitioning conflicts with the fundamental principles of EU law underlying the establishment and functioning of the internal market.

Despite the controversial effects on the internal market, the current marketing prohibition of tobacco products for oral use is established in the Tobacco Products Directive, which for one has its legal basis in what is now Article 114 TFEU. A measure can be based on Article 114 TFEU only if it has as its objective the establishment and functioning of the internal market. Interestingly however, the EU-wide ban on tobacco for oral use seems to be predominantly pursuing public health objectives rather than internal market aims. Complexity is not removed by the fact that Article 168 TFEU entitles the EU to complementary competence only, and explicitly excludes EU competence in course of harmonising public health related matters, such as tobacco regulation.

Due to the foregoing, it is only natural that the Tobacco Products Directive and the ban on tobacco products for oral use, in particular, has been challenged in several occasions. In an equal amount of occasions, the CJEU has upheld the validity of the Directive. However, the reasoning of the CJEU in the cases concerned has not always been considered adequate in all relevant aspects.

This thesis examines the historical development of tobacco products regulation in the EU, and analyses the current regulatory state with a particular emphasis on the marketing ban on tobacco products for oral use. The analysis includes evaluation of the appropriateness of Article 114 TFEU as the legal basis of the Tobacco Products Directive and examination of the EU competence in matters relating to public health, on theoretical

point of view as well as on a more practical point of view through case studies. Finally, the potential effects of the currently on-going revision of the Directive are analysed.

## 2 Political and Legislative Background

In order to understand the underlying rationale for the present state of tobacco regulation in the EU, one has to look at the development of both political and legislative circumstances prevailing in Europe over time.

The EU legislation regulating the marketing and production of tobacco products can be divided into three main areas: first, *labelling* – consumer protection by providing sufficient information and warnings on the respective products; second, *lawful contents* – consumer protection by regulating the composition of tobacco products; and third, *advertising* – measures regulating the advertising products rather than the tobacco products itself.<sup>1</sup> The following sections concentrate mainly on the first two areas, while reference of a general nature is also made to the third.

This chapter provides an overview of the development of EU policies relating to tobacco products regulation, and presents the pattern of secondary legislation that has led to the present legal state. Finally, the most relevant piece of secondary legislation in today's EU tobacco regulation is discussed.

### 2.1 EU Policy on Tobacco Consumption

The EU policy on tobacco consumption closely resembles the policy adopted at the international level by the World Health Organisation (WHO). This is evident since the EU is, according to the Treaty, under an obligation to cooperate with the competent international organisations in matters relating to public health.<sup>2</sup>

The Commission has emphasised the WHO's role in public health matters by acknowledging it as a *key partner* in international cooperation.<sup>3</sup> Since 2005, the EU is a party to the WHO Framework Convention on Tobacco Control (FCTC),<sup>4</sup> whose primary focus is on the continuous and substantial reduction of tobacco use.<sup>5</sup> Ultimately, the WHO's objective in tobacco

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<sup>1</sup> T. Hervey et al., *Health Law and the European Union*, Cambridge University Press, 2004, p. 374.

<sup>2</sup> Article 168(3) TFEU.

<sup>3</sup> Communication from the Commission, COM(2000) 285 final, p. 16.

<sup>4</sup> WHO, Parties to the FCTC, available at

[http://www.who.int/fctc/signatories\\_parties/en/index.html](http://www.who.int/fctc/signatories_parties/en/index.html), accessed on 22 February 2012.

<sup>5</sup> WHO Framework Convention on Tobacco Control, Article 3.

control is, quite ambitiously, *un monde sans tabac* – a world without tobacco.<sup>6</sup>

When it comes to European tobacco control, the first concrete manifestation of the obligation to cooperate with the WHO took place in 1990 through the adoption of a Council Decision relating to cancer prevention.<sup>7</sup> The Decision formed part of the first European initiative in the field of tobacco control, the *Europe against Cancer* programme, launched in 1985 and followed by the adoption of its framework.<sup>8</sup>

The Europe against Cancer programme aimed at a significant 15% decrease in deaths caused by cancer in Europe by the year 2000. The objective was to be achieved through the primary focus on prevention and health education, medical research, informing the public and training medical personnel.<sup>9</sup> In 1995, the Commission noted significant progress brought about by the programme,<sup>10</sup> but a final review in 2003 reported that the ambitious objective had not been met even though the results, in general, showed remarkable reductions in cancer deaths.<sup>11</sup> However, as to deaths caused by tobacco products specifically, the number had continued to increase substantially and further Union action was expected.<sup>12</sup>

Indeed, there have been almost thirty individual health-promoting anti-tobacco projects funded by the Commission since the conclusion of the Europe against Cancer programme.<sup>13</sup> The main principles included in the programme have also continued to be pursued within the public health frameworks<sup>14</sup> adopted in 2003 and 2008.

There are multiple reasons for adopting soft law measures in public health related issues at the EU level rather than merely nationally. For instance, the EU may provide financial resources for cross-border health policy projects, which renders their implementation more likely. Such cross-border projects may also have an indirect impact on health policies adopted at purely national level. Finally, the EU soft law has also played an important informative role as the basis for secondary legislation in the field of tobacco regulation.<sup>15</sup>

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<sup>6</sup> S. Crosby, *The new Tobacco Control Directive: an illiberal and illegal disdain for the law*, E.L. Rev. 2002, 27(2), p. 183.

<sup>7</sup> Decision 90/238/Euratom, ECSC, EEC, adopting a 1990 to 1994 action plan in the context of the 'Europe against Cancer' programme, OJ L 137, Article 1(4).

<sup>8</sup> Communication from the Commission, COM(90) 185 final, p. 1.

<sup>9</sup> Ibid.

<sup>10</sup> Report from the Commission, COM(95) 356 final, p. 2.

<sup>11</sup> P. Boyle et al., *Measuring progress against cancer in Europe: has the 15% decline targeted for 2000 come about?*, Ann. Oncol. 2003, 14(8), p. 1312.

<sup>12</sup> Communication from the Commission, COM(96) 609 final, p. 1.

<sup>13</sup> European Commission, Public Health, Tobacco – Projects, available at [http://ec.europa.eu/health/tobacco/projects/index\\_en.htm](http://ec.europa.eu/health/tobacco/projects/index_en.htm), accessed on 10 March 2012.

<sup>14</sup> Decision No 1786/2002/EC adopting a programme of Community action in the field of public health, OJ L 271 and Decision No 1350/2007/EC establishing a second programme of Community action in the field of health, OJ L 301.

<sup>15</sup> T. Hervey et al., *Health Law and the European Union*, supra note 1, p. 374.

Today, although the number of smokers has been decreasing, tobacco use remains the *largest avoidable health risk in Europe*.<sup>16</sup> It is not surprising, therefore, that the EU is once again on the verge of revising the respective secondary legislation. Having touched upon the secondary legislation on tobacco products, it is natural to turn to the analysis of the development thereof.

## 2.2 Development of Secondary Legislation

The early implementation of the Europe against Cancer programme rapidly led to the adoption of secondary legislation regulating tobacco products. In 1989, the Council adopted the first harmonising Directive concerning the labelling of tobacco products.<sup>17</sup>

Fundamentally, the Directive was based on Article 100a EEC [114 TFEU] as amended by the Single European Act, which seeks to ensure the establishment and functioning of the internal market. Accordingly, the recitals of the Directive emphasised the need to eliminate the potential barriers to free movement of tobacco products resulting from differences between labelling regulations of the Member States, which for one were likely to impede the establishment and operation of the internal market.<sup>18</sup>

In addition to the free movement based approach, the Directive also referred to public health objectives. It recognised the importance of the Europe against Cancer programme and stressed the necessity of health warnings on tobacco products as a vital factor in public health protection.<sup>19</sup> In essence, this kind of dual objective is not unusual in harmonising legislation touching upon both the functioning of the internal market and the protection of public health,<sup>20</sup> but is in fact even encouraged by Article 114(3) TFEU.

The actual substance of the Directive was limited to harmonising the indication of tar and nicotine yields as well as health warnings on tobacco unit packets,<sup>21</sup> but the most relevant element in the present context lies in Article 2(1) of the Directive – the definition of *tobacco products*. Tobacco products within the meaning of the Directive included all *products for the purpose of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco*.<sup>22</sup> Thus, the Directive did not draw a

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<sup>16</sup> European Commission, Public Health, Tobacco – Policy, available at [http://ec.europa.eu/health/tobacco/policy/index\\_en.htm](http://ec.europa.eu/health/tobacco/policy/index_en.htm), accessed on 10 March 2012.

<sup>17</sup> Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products, OJ L 359.

<sup>18</sup> *Ibid.*, recitals 1 and 2.

<sup>19</sup> *Ibid.*, Article 1, recitals 4 and 6.

<sup>20</sup> T. Hervey et al, *Health Law and the European Union*, supra note 1, p. 47.

<sup>21</sup> Directive 89/622/EEC, supra note 17, Articles 3 and 4.

<sup>22</sup> *Ibid.*, Article 2(1).

distinction between different kinds of tobacco products. Be it cigarette or smokeless tobacco, the health warning requirement was equally applicable to both. One might argue that such approach is only logical: if a product contains tobacco, it is to be regarded as a tobacco product.

Only a few months later, a new Directive<sup>23</sup> was adopted. It specifically targeted cigarettes by harmonising their maximum allowed tar yield. Again, the Directive was based on what is now Article 114 TFEU and included references to both obstacles to trade and public health matters.<sup>24</sup> Most significantly, however, the gradual reduction of tar yield contained in cigarettes was the first concrete step towards the regulatory differentiation between diverse tobacco products.

The 1992 amending Directive<sup>25</sup> – also based on what is now Article 114 TFEU in line with its predecessors – decisively blurred the logical and indistinctive approach to tobacco products. In addition to the original definition of tobacco products, the Directive specifically defined *tobacco for oral use* as *all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms – particularly those presented in sachet portions or porous sachets – or in a form resembling a food product*. Having first differentiated tobacco products for oral use from other tobacco products, the Directive prohibited the marketing of tobacco products falling within the definition.<sup>26</sup>

Unsurprisingly, the wording of the definition has faced criticism for being ambiguous. Moreover, it has been argued that the definition was carefully drafted with a view to maintaining a market for other smokeless tobacco products that already existed in the internal market. As a result, the definition extra-ordinarily focuses on a special form of a harmful substance and not the substance itself – the distinctive characteristic of tobacco products for oral use that differentiates it from other smokeless tobacco products is its water content. Thus, tobacco products such as dry snuff for nasal consumption and chewing tobacco fell outside the definition and, seemingly deliberately, remain in free circulation.<sup>27</sup>

As Lidgard points out, the definition as it now stands leaves room for questions relating to its interpretation. Would a tobacco product for oral use escape the prohibition if it was marketed for nasal consumption, while in

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<sup>23</sup> Directive 90/239/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes, OJ L 137.

<sup>24</sup> *Ibid.*, recitals 1 and 3.

<sup>25</sup> Directive 92/41/EEC amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products, OJ L 158.

<sup>26</sup> *Ibid.*, Articles 1(2) and 1(5).

<sup>27</sup> H. Lidgard, *Swedish snus confronts basic EU principles* in G. Melander et al., *Modern issues in European law: Nordic perspectives: essays in honour of Lennart Pålsson*, Norstedts juridik, 1997, pp. 130 and 140.

fact used orally?<sup>28</sup> Due to the inherent element of intent in the definition, the answer seems to be in the negative. By analogy, in case an oral tobacco product is marketed as chewing tobacco, but it is *evident that the product is not meant to be chewed*, it cannot escape the present prohibition.<sup>29</sup>

The express rationale for the differentiation between tobacco for oral use and other tobacco products may be found by having regard to the spirit of the Directive's preamble, which was driven by concerns relating to public health. They pointed out, *inter alia*, that the introduction in the internal market of *new tobacco products for oral use*, as defined above, was particularly attractive to young people and, thus, was likely to lead to their nicotine addiction.<sup>30</sup> Reference was also made to, at the time recent, studies, according to which tobacco for oral use contains large quantities of carcinogenic substances that cause cancer.<sup>31</sup> Therefore, and having regard to the fact that the preceding European Conference on Tobacco and Health had suggested banning all new tobacco products,<sup>32</sup> it seems obvious that the rationale for distinguishing between traditional *tobacco products* and *tobacco for oral use* was to confront the detrimental effects of the latter on public health.

Materially, the only notion touching upon the functioning of the internal market was the argument that the sales ban adopted by three Member States affected the operation of the internal market.<sup>33</sup> The seemingly secondary nature of free movement based concerns compared with public health concerns may appear odd, especially so if one recalls that Article 114 TFEU as the Directive's legal basis is primarily aimed at improving free movement in the internal market. Such approach adopted by the EU legislature has not completely escaped criticism. For instance, it has been argued that *the fact that some Member States are adopting policies that the relevant majority on the European level disagrees with is not a reason for the EU to step in*.<sup>34</sup>

Be it as it may, the adopted method of confronting the health effects was very different from that of the previous Directive, which approached the issue by regulating the contents of tobacco products. In effect, the 1992 Directive imposed a total ban on the marketing of tobacco for oral use by establishing that the *Member States shall prohibit the placing on the market of tobacco for oral use*.<sup>35</sup> In addition, the Directive imposed an obligation on the Member States to ensure that all smokeless tobacco products carried a specific warning: *Causes cancer*.<sup>36</sup>

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<sup>28</sup> Ibid., p. 140.

<sup>29</sup> Opinion of Advocate General Geelhoed in Case C-434/02 *Arnold André GmbH & Co. KG v Landrat des Kreises Herford* [2004] ECR I-11825, para 40.

<sup>30</sup> Directive 92/41/EEC, supra note 25, recitals 13 and 15.

<sup>31</sup> Ibid., recital 16.

<sup>32</sup> T. Hervey et al, *Health Law and the European Union*, supra note 1, p. 376.

<sup>33</sup> Directive 92/41/EEC, supra note 25, recital 17.

<sup>34</sup> M. Kumm, *Constitutionalising Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union*, *European Law Journal*, Vol. 12, No. 4, 2006, p. 520.

<sup>35</sup> Directive 92/41/EEC, supra note 25, Article 1(5).

<sup>36</sup> Ibid., Article 1(3)(b).

The marketing prohibition, as it stood, was subsequently transferred to the recasting Tobacco Products Directive,<sup>37</sup> which today forms the substance of European harmonised tobacco products regulation. An analysis of the Directive is presented below.

## 2.3 Tobacco Products Directive

The 2001 Tobacco Products Directive explicitly seeks to clarify the state of EU-level tobacco regulation.<sup>38</sup> The previous Directives had failed to establish a solid standard of harmonisation, which is highlighted by the fact that the tobacco industry had been successful in circumventing or finding weaknesses in the harmonising measures.<sup>39</sup> For instance, health warnings had been printed in gold lettering, which resulted in a minimal contrast, and the producers were increasing the addictive effect of nicotine by using different additives.<sup>40</sup> Moreover, despite the free movement clause in the previous Directives aimed at ensuring the free movement of compliant tobacco products, the Member States retained the possibility to introduce more stringent product requirements on imported tobacco products, due to which satisfactory harmonisation had not been achieved.<sup>41</sup> Thus, the Tobacco Products Directive endeavours to establish the regulation of manufacture, labelling and sale of tobacco products under a single piece of secondary legislation.

In conformity with the previous Directives, the Tobacco Products Directive also has the functioning of the internal market as its legal basis, namely Article 95 EC [114 TFEU]. The explicit division of internal market and public health concerns, however, differs from that of the preceding Directives, with a visible emphasis on the former. As a result and in terms of legislative drafting, notions promoting public health are clearly of a secondary priority compared with the previous Directives. According to Hervey,<sup>42</sup> this is a direct consequence of the Court's judgment in the *Tobacco Advertising I* case,<sup>43</sup> which annulled the 1998 Directive<sup>44</sup> on tobacco advertising due to the fact that it included various provisions that

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<sup>37</sup> Directive 2001/37/EC 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.

<sup>38</sup> *Ibid.*, recital 1.

<sup>39</sup> M. McKee et al, *Public Health Policies* in E. Mossialos et al, *Health Systems Governance in Europe: the role of EU law and policy*, Cambridge University Press, 2010, p. 265.

<sup>40</sup> *Ibid.*, p. 265-266.

<sup>41</sup> T. Hervey, *Up in Smoke? Community (anti) tobacco law and policy*, *European Law Review*, 26(2), 2001, p. 104.

<sup>42</sup> T. Hervey et al, *Health Law and the European Union*, *supra* note 1, p. 375.

<sup>43</sup> Judgment of the Court in Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419.

<sup>44</sup> Directive 98/43/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ L 213.

were ill-suited to be adopted under Article 100a EEC [114 TFEU].<sup>45</sup> Indeed, the legal basis of the Tobacco Products Directive was questioned even prior to its adoption in the preparatory procedure, mainly on the basis of the ruling in *Tobacco Advertising I*.<sup>46</sup>

Despite the apparent secondary role of public health concerns in the recitals, the actual substance of the Tobacco Products Directive is clearly health and consumer protection oriented. The Directive's tobacco regulation mainly relates to the lowering of maximum allowed levels of harmful substances in tobacco products, and strengthening the labelling requirements and health warnings for cigarettes, in particular. In addition, the packaging of tobacco products is regulated more strictly than in the previous Directives by prohibiting descriptors such as *light* or *mild*, which may *mislead the consumer into the belief that such products are less harmful*. According to Crosby, none of the aforementioned measures can be said to have a visible internal market objective, even though Article [114 TFEU] as the Directive's legal basis so requires.<sup>47</sup>

As for tobacco for oral use, the current regulatory state is established in Article 8 of the Tobacco Products Directive. The marketing ban imposed by the previous Directive remains identical, with one significant exception: it is to be applied *without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden*.<sup>48</sup> Article 151 of the Act provides that the stipulations laid down in Annex XV apply, in respect of the new Member States, under the conditions therein.<sup>49</sup> Finally, Annex XV under the subheading Miscellaneous establishes that the ban does not apply in Sweden and Norway.<sup>50</sup> That is to say, Sweden is the only EU Member State maintaining an exception from the EU-wide sales ban, with Norway enjoying the same position as a member of the EEA.

The exception does not mean, however, that Sweden and Norway would have the exclusive right to place tobacco for oral use into commercial circulation within the internal market. Quite the opposite, the exception is followed by an obligation on Sweden and Norway to take *all measures necessary to ensure that [tobacco for oral use] is not placed on the market in the Member States*.<sup>51</sup>

Consequently, having regard to the most fundamental principles behind the creation of the internal market in the EU, the present scenario may well be described as unique. As the Swedish Minister for Trade, Ewa Björling, has duly pointed out, following the ban there seems to be *only one commodity*

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<sup>45</sup> C. Barnard, *The Substantive Law of the EU – The Four Freedoms*, Oxford University Press, 2010, p. 609.

<sup>46</sup> M. McKee et al, *Public Health Policies*, supra note 39, p. 266.

<sup>47</sup> S. Crosby, *The new Tobacco Control Directive: an illiberal and illegal disdain for the law*, supra note 6, pp. 180-182.

<sup>48</sup> Directive 2001/37/EC, supra note 37, Article 8.

<sup>49</sup> Act of Accession of Austria, Finland and Sweden, OJ 94/C 241, Article 151.

<sup>50</sup> *Ibid.*, Annex XV, X. Miscellaneous.

<sup>51</sup> *Ibid.*

*that is lawfully produced, sold and consumed in one Member State, and exported all over the world, that still cannot be sold in the rest of the EU – tobacco for oral use.*<sup>52</sup>

Finally, as to the labelling of tobacco products for oral use and other smokeless tobacco products, the specific *Causes cancer* warning required by the previous Directive has been replaced by a less dramatic warning: *This tobacco product can damage your health and is addictive.*<sup>53</sup> When it comes to tobacco products for oral use, naturally, such requirement is specifically applicable in Sweden only, where the marketing of tobacco products for oral use remains allowed. The recitals of the Tobacco Products Directive do not state reasons for the significant change in the substance of the health warning. One has to look back to the Proposal for the Tobacco Products Directive in order to find the explanation. According to the Proposal, *scientific opinion no longer supports a strong warning.*<sup>54</sup>

As mentioned in section 2.1, the Tobacco Products Directive is currently under a revision procedure. A more detailed analysis of the potential effects of the revision follows in chapter 6. First, however, since the Tobacco Products Directive is adopted by having recourse to Article [114 TFEU], the following chapter examines the legal conditions required for basing a measure thereon.

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<sup>52</sup> Swedish Minister for Trade E. Björling, *Snuffing out snus?*, European Voice, Debattartikel, 7 April 2009, available at <http://www.regeringen.se/sb/d/10008/a/124087>, accessed on 3 May 2012.

<sup>53</sup> Directive 2001/37/EC, *supra* note 37, Article 5(4).

<sup>54</sup> Proposal for a Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, COM/99/0594 final – COD 99/0244, OJ C 150 E, recital 14.

## 3 Article 114 TFEU as the Legal Basis

As pointed out in the preceding section, the Tobacco Products Directive has Article 95 EC [114 TFEU] as its legal basis. Article 114(1) TFEU provides that *the European Parliament and the Council shall [...] adopt the measures for the approximation of the provisions laid down by law [...] in Member States which have as their object the establishment and functioning of the internal market.*

In addition to the internal market approach, Article 114(3) TFEU requires *a high level of protection* in measures concerning *health [...] and consumer protection*. In pursuing such protection, Article 114(3) TFEU further obliges the EU legislature to take into account *any new development based on scientific facts*. That is, any harmonising measure seeking to improve the conditions of the internal market that at the same time affects health and consumer protection should, in principle, have a dual objective.

This chapter examines the preconditions for a measure in order for it to be correctly based on Article 114 TFEU. In course of evaluation, the complexity of fulfilling the required dual objective is addressed, and the suitability of Article 114 TFEU as the legal basis for the Tobacco Products Directive is questioned.

### 3.1 Contribution to the Internal Market

Article 114(1) TFEU sets a clear requirement for any harmonising measure to be adopted by having recourse thereto: the objective of such measure must be to improve the functioning of the internal market or, as Wyatt puts it, contribute to the internal market to a certain extent.<sup>55</sup>

The CJEU has, in their case law, recognised two main factors to be taken into account in evaluating whether a harmonising measure is connected to the establishment and functioning of the internal market. First, the measure may seek to remove an obstacle to trade or, second, it may seek to prevent a distortion of competition.<sup>56</sup> In this context, the effect of the measure is also a decisive factor: the measure must actually contribute to the removal of existing or potential obstacles to trade or competition.<sup>57</sup> In case one of these

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<sup>55</sup> D. Wyatt, *Community Competence to Regulate the Internal Market*, University of Oxford Faculty of Law Legal Studies Research Paper Series, Working Paper No 9/2007, 2007, p. 46.

<sup>56</sup> M. Kumm, *Constitutionalising Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union*, supra note 34, p. 507.

<sup>57</sup> D. Slater, *The scope of EC harmonising powers revisited?*, German Law Journal, Vol. 04, No. 02, 2003, p. 140.

factors is satisfied, the measure can be considered to have as its objective the establishment and functioning of the internal market.<sup>58</sup>

Ordinarily, the differences in national laws of the Member States constituting obstacles to trade would be removed by setting a harmonised, EU-wide minimum standard with which a particular product has to comply in order for it to be marketed in the internal market.<sup>59</sup> Less ordinarily, such obstacles to trade would be removed by imposing an unconditional EU-wide ban on that particular product, which happens to be the case in the context of tobacco for oral use.

At present, the regulation of labelling and lawful contents of tobacco products and cigarettes, in particular, is an excellent example of the former approach. The Tobacco Products Directive sets a harmonised standard for the labelling requirements and for the maximum allowed yields of tar, nicotine and carbon monoxide.<sup>60</sup> Such harmonisation obviously seeks to remove the potential obstacles to trade, which would otherwise be brought about by different product requirements in each Member State. Consequently, it seems safe to argue that, as regards the labelling and contents regulation, the Tobacco Products Directive does actually contribute to the internal market.<sup>61</sup>

As to the latter approach of banning a product, it is appropriate to note that in specific circumstances a certain kind of ban may serve the purpose of contributing to the internal market to the extent that it rightfully has Article 114 TFEU as its legal basis. As an example, the Directive on the safety of toys prohibits the Member States from placing on the market toys that do not comply with the safety requirements laid down in the Directive.<sup>62</sup> The harmonisation of toy safety requirements clearly removes obstacles to trade that would arise if there were disparities between national laws relating to toy safety.<sup>63</sup> Therefore, the marketing ban on certain toys constitutes a means of ensuring that only compliant products end up in free circulation in the internal market and, consequently, contributes to the internal market.<sup>64</sup>

When it comes to the marketing ban imposed on tobacco for oral use, it is difficult to argue that similar rationale exists. To start with, the marketing ban is unconditional and applicable to every form of tobacco for oral use.

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<sup>58</sup> M. Kumm, *Constitutionalising Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union*, supra note 34, p. 507.

<sup>59</sup> C. Barnard, *The Substantive Law of the EU – The Four Freedoms*, supra note 45, p. 609.

<sup>60</sup> Directive 2001/37/EC, supra note 37, Article 3.

<sup>61</sup> For a differing opinion, see H. Liu, *Harmonizing the Internal Market, or Public Health? – Revisiting Case C-491/01 (British American Tobacco) and Case C-380/03 (Tobacco Advertising II)*, Columbia Journal of European Law Online, Vol. 15, 2009, p. 42. Liu argues that even though the Directive includes a free movement clause, the Member States retain discretion to lay down more stringent product requirements than those provided in the Tobacco Products Directive. Thus, the Directive is not sufficient means to eliminate differences between national laws.

<sup>62</sup> Directive 2009/48/EC on the safety of toys, OJ L 170, Article 10.

<sup>63</sup> D. Wyatt, *Community Competence to Regulate the Internal Market*, supra note 55, p. 7.

<sup>64</sup> *Ibid.*

This is to say that a common European standard with which a tobacco product for oral use would have to comply in order to be marketed in the internal market does not exist. Moreover and as mentioned above, the obstacles to trade in this context were originally created by sales bans adopted in three Member States.<sup>65</sup> Instead of seeking to remove the actual obstacles and contributing to the internal market, one could argue that the EU-wide sales ban constitutes an obstacle itself, whose aim is to prevent a market from developing in the first place.<sup>66</sup> Consequently, it has been argued that, unlike the ban on certain unsafe toys, for example, the ban imposed on tobacco for oral use *does not appear to make any contribution to the free movement of goods*.<sup>67</sup>

In *Swedish Match*,<sup>68</sup> the CJEU had the opportunity to rule on the marketing ban on tobacco for oral use and, in particular, on whether the ban actually contributes to the internal market. The CJEU carefully adapted to the wordings presented in the recitals of the Tobacco Products Directive and Directive 92/41/EEC, and concluded that the bans adopted by three Member States were likely to lead to a *heterogeneous development of conditions of marketing of tobacco products for oral use*.<sup>69</sup> This, according to the CJEU constituted obstacles to trade *per se*.<sup>70</sup> However, the CJEU did not rule on the essential question of how and on what basis exactly the EU-wide marketing ban actually contributes to the functioning of the internal market.

To that effect, AG Geelhoed has provided an interesting view in his Opinion in *André*.<sup>71</sup> Admitting that by banning a specific product the existence of a lawful market is made impossible, he points out that the requirement of certain contribution to the internal market needs to be interpreted broadly. According to AG Geelhoed, a harmonising measure must, as is well known by now, contribute to the conditions for the functioning of the internal market, but this does not imply that it has to do so *in respect of every individual product*.<sup>72</sup> Thus, he argues, the marketing ban on certain tobacco products for oral use is capable of contributing to the conditions of the internal market in other products in that the *effort to control the marketing of other smokeless tobacco products can be reduced*.<sup>73</sup> One might conclude, however, that much weight should not be placed on this final argument due to its unclear nature. An in-depth analysis of both *André* and *Swedish Match* follows in chapter 5.

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<sup>65</sup> Directive 92/41/EEC, *supra* note 25, recital 17.

<sup>66</sup> G. Howells, *The Tobacco Challenge: Legal Policy and Consumer Protection*. Ashgate Publishing, Ltd., 2011, p. 227.

<sup>67</sup> D. Wyatt, *Community Competence to Regulate the Internal Market*, *supra* note 55, p. 8.

<sup>68</sup> Judgment of the Court in Case C-210/03 *Swedish Match AB and Swedish Match UK Ltd v Secretary of State for Health* [2004] ECR I-11893.

<sup>69</sup> *Ibid.*, paras 37, 39-40.

<sup>70</sup> *Ibid.*, para 38.

<sup>71</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, *supra* note 29.

<sup>72</sup> *Ibid.*, paras 78-79.

<sup>73</sup> *Ibid.*, para 79.

In addition to the obstacles to trade approach, the second ground for relying on Article 114 TFEU as the legal basis is to prevent a distortion of competition. At a glance and recalling that *any obstacle to trade is also likely to distort competition*, it can be argued that the two factors are overlapping to a certain extent.<sup>74</sup> On the other hand, however, the distortion of competition as a concept is broader in that it applies also to situations where one producer enjoys a competitive advantage over another due to regulatory differences between two respective Member States.<sup>75</sup>

Unfortunately, the potential applicability of the competition-related ground to the marketing ban of tobacco for oral use has never been considered by the CJEU in their case law. However, it suffices to note that since the two respective grounds are not cumulative, the ruling on the potential distortion of competition would not have changed the outcome of the CJEU's finding in *Swedish Match* that the marketing ban can be considered to contribute to the internal market.

In the following section, the second element inherent in the application of Article 114 TFEU as a measure's legal basis is evaluated, namely that of health and consumer protection.

### 3.2 High Level of Health and Consumer Protection

According to Article 114(3) TFEU, the EU institutions must ensure a high level of protection in their harmonising measures concerning health and consumer protection. The harmonisation of tobacco products regulation undoubtedly concerns health and consumer protection, which is also apparent in the recitals of the respective Directives as presented above.

Even though health and consumer protection must constitute an inherent part of any relevant harmonising measure adopted on the basis of Article 114 TFEU, one might ask whether that Article is suitable for adopting a measure whose primary objective is the protection of health and consumer, leaving the functioning of the internal market as a secondary one. According to the CJEU, the answer is positive. It has been established by the CJEU that as long as the harmonising measure actually contributes to the conditions of the internal market, the EU institutions cannot be prevented from relying on Article 114 TFEU as the legal basis solely on the ground that public health is a *decisive factor* in the measure.<sup>76</sup> In other words, even if the main objective of a harmonising measure adopted under Article 114 TFEU is

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<sup>74</sup> C. Barnard, *The Substantive Law of the EU – The Four Freedoms*, supra note 45, p. 610.

<sup>75</sup> Ibid.

<sup>76</sup> Judgment of the Court in Case C-491/01 *The Queen v Secretary of State for Health, ex parte: British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd* [2002] ECR I-11453, para 62. Case C-210/03 *Swedish Match*, supra note 68, para 31.

health protection, the measure *will nevertheless be valid provided that it makes some contribution to internal market aims*.<sup>77</sup>

In harmony with the CJEU's considerations, AG Geelhoed has referred to the competence enjoyed by the EU institutions in relation to the use of Article 114 TFEU as a *functional competence*.<sup>78</sup> In exercising functional competence, the ultimate objective of the harmonising measure does not bear relevance, be it the protection of public health or any other. What does matter, for one, is *whether a measure is appropriate to facilitate trade*.<sup>79</sup>

Contrary to the functional approach adopted by the CJEU and AG Geelhoed, it has been argued that Article 114 TFEU cannot be used as a legal basis for measures pursuing health protection aims. Such argument seeks support from the premise of a purely free movement based nature of Article 114(1) TFEU, on one hand, and from a clearly subordinate nature of Article 114(3), on the other. Having regard to the fundamental status of free movement principles it has been stated that those principles may not be negated on pure health protection grounds. Particularly strong criticism has been presented against the use of Article 114 TFEU as the basis for health protection measures, which go as far as prohibit the marketing of a specific product in the internal market. Such prohibition may be considered *the very antithesis of ensuring the free movement*, which leads to the conclusion that *Article [114 TFEU] cannot be used to ban products entirely on grounds of health protection*.<sup>80</sup>

Acknowledging, however, that the EU legislature has received support from the established case law for the conclusion that public health concerns can dominate a measure adopted under Article 114 TFEU, the remaining issue in the context of the sales ban of tobacco for oral use as a means of protecting health and consumer seems to be the following: What would be the consequences on public health of the free movement of tobacco for oral use in the internal market? On one hand, the effect might be substitutive in nature, thus encouraging consumers to give up smoking. On the other hand, the effect might be that of a steppingstone, making it easier for consumers to start tobacco consumption.<sup>81</sup> This aforementioned uncertainty as to the potential health effects of the free circulation of tobacco products for oral use has underlined the discussion on the appropriateness of a sales ban as a measure seeking to protect health and consumer.<sup>82</sup>

Scientific evidence on the health effects of tobacco for oral use vary to a large extent, but what has been acknowledged as an objective consensus is

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<sup>77</sup> D. Wyatt, *Community Competence to Regulate the Internal Market*, supra note 55, p. 15.

<sup>78</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29, para 73.

<sup>79</sup> *Ibid.*

<sup>80</sup> S. Crosby, *The Single Market and the Rule of Law*, E.L. Rev. 1991, 16(6), p. 458.

<sup>81</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29, para 89.

<sup>82</sup> *Ibid.*, para 95. See also Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion on the Health Effects of Smokeless Tobacco Products, 2008, p. 11.

that it is, by far, less harmful than cigarettes.<sup>83</sup> In light of the foregoing, the ban on an individual tobacco product intended to ensure a high level of protection of health and consumer seems quite hypocritical, especially so while all other tobacco products – including smokeless tobacco products – remain in free circulation in the internal market. It is not disputed that tobacco for oral use may cause health risks, but such risks exist for all tobacco products, which is why *it is hard to see how oral tobacco can be singled out from other tobacco products*.<sup>84</sup>

When it comes to the EU legislature's obligation laid down in Article 114(3) TFEU to take continuously into account new scientific development, the current situation with tobacco for oral use is twofold. As regards labelling requirements, the Tobacco Products Directive duly respects the development of scientific evidence by having downgraded the required health warning on tobacco products for oral use, as pointed out above. Interestingly however, the developed scientific opinion has not resulted in a revision of the actual sales ban of tobacco products for oral use. On the contrary, the recitals of the Tobacco Products Directive do not even mention the concrete reasons for the ban. Consequently, it seems that the scientific development – which did form an essential element for the ban in the first place – has been overlooked in the context of transferring the marketing ban of tobacco for oral use to the Tobacco Products Directive.

AG Geelhoed has emphasised the importance of reviewing legislation in case new scientific evidence occurs. In that regard, he has noted that the obligation to review becomes even more crucial in the event of a fundamental amendment to the relevant legislation. Accordingly, all measures relating to different tobacco products have to be subjected to a review where fundamental amendments are made to the EU tobacco legislation.<sup>85</sup> On one hand, and in the absence of unanimous scientific evidence, such reasoning seems to support the finding that inadequate attention has been paid to a potential review of the ban on tobacco products for oral use. On the other hand, the foregoing would also mean that the ongoing revision of the Tobacco Products Directive has to include a substantial overall review of the ban.

Having considered aspects relating to health and consumer protection in the adoption of EU secondary legislation aimed at improving the functioning of the internal market, it is relevant to confine oneself to examining the EU-level regulation in the area of public health.

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<sup>83</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29, para 49.

<sup>84</sup> G. Howells, *The Tobacco Challenge: Legal Policy and Consumer Protection*, supra note 66, p. 227.

<sup>85</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29, para 93.

## 4 Harmonisation relating to Public Health

In general, regulating matters affecting public health at the European level involves a considerable amount of uncertainty. Such uncertainty derives from the overlapping and partly controversial nature of certain Treaty articles.

First, Article 5(2) TEU establishes the *principle of conferral*, according to which the EU may act only within the limits of the competences conferred upon it by the Member States. This is to say, naturally, that competences not explicitly conferred upon the EU in the Treaty remain with the Member States.

Second, Article 168 TFEU lays down the basis for public health regulation in the EU. According to Article 168(1), any EU action directed to improving public health *shall complement national policies*. The wording is clear on the division of competences between the EU and the Member States: public health measures adopted at the EU level should be complementary in nature and leave the fundamental choices for the Member States to be made. Article 168(5) further excludes EU competence and emphasises the Member States' status as the main operators in the field of public health. It provides that the EU institutions may adopt *measures which have as their direct objective the protection of public health regarding tobacco*, however, and this is of central importance: *excluding any harmonisation of the laws and regulations of the Member States*.

Finally, as has been pointed out above, Article 114(3) TFEU sets an obligation on the EU institutions to ensure a high level of health and consumer protection in their harmonising measures adopted under that Article.

This chapter evaluates the controversy between the foregoing Treaty provisions, and presents the issues relating to the setting of limits to the legislative competence enjoyed by the EU legislature.

### 4.1 Interplay between Articles 114(3) and 168 TFEU

Separately considered, the aforementioned Treaty stipulations may not raise suspicions as to their clarity. Having read them together, however, one might accept that EU competence in the field of public health constitutes a somewhat grey area.

On one hand, Article 168(5) explicitly excludes the EU legislature's competence in harmonising measures affecting public health. Thus, any EU measure relating to public health should only be complementary in nature and, supported by the principle of conferral, leave the fundamental decisions for the Member States. On the other hand, such measures should, at the same time, reflect a high level of health and consumer protection as required by Article 114(3) TFEU. The controversy is evident, as highlighted by Kumm: *Article [114(3) TFEU] specifically states that a high level of health protection should be taken as a basis for deciding the content of harmonising legislation, where public health issues are affected, even though the Treaty explicitly determines that public health grounds by themselves do not justify the enactment of harmonising legislation.*<sup>86</sup>

The CJEU has sought to establish in their case law a pattern for balancing between the requirements in Article 114(3) and 168(5). In *Tobacco Advertising I*, the CJEU ruled that the exclusion in Article [168(5) TFEU] does not bar the EU legislature from adopting – on the basis of other Treaty provisions – measures having impact on the protection of public health. However, the CJEU continued that the use of other Treaty provisions as a legal basis with a view to circumventing that exclusion is prohibited. Finally, to make the pattern even more ambiguous, the CJEU pointed out that in case the conditions for relying on Article [114 TFEU] are fulfilled, the EU legislature cannot be prevented from relying on that Article as a legal basis solely on the ground that public health concerns form a decisive factor therein.<sup>87</sup>

It is interesting to evaluate the Tobacco Products Directive in light of the foregoing. Naturally, having Article 114 TFEU as its legal basis, the Directive duly refers to the obligation to ensure a high level of health and consumer protection laid down in Article 114(3) TFEU.<sup>88</sup> However, references to Article 168 TFEU are left to a minimum, with only superficial notions touching upon the integration of EU health requirements in other EU policies, in general.<sup>89</sup> Such circumvention of the explicit exclusion of EU competence in harmonising public health matters has been strongly criticised. According to Crosby, *Article [114(1) TFEU] is clearly being misused* since, as long as the EU does not enjoy harmonising competence in the area of public health, it cannot validly adopt secondary legislation such as the Tobacco Products Directive.<sup>90</sup> Moreover, Crosby does not find the circumvention merely incidental, but argues that *the ultimate purpose of the [Directive] is [...] to arrogate health legislative powers to the [EU] which it does not have.*<sup>91</sup>

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<sup>86</sup> M. Kumm, *Constitutionalising Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union*, supra note 34, pp. 506-507.

<sup>87</sup> Case C-376/98 *Tobacco Advertising I*, supra note 43, paras 77-79 and 88.

<sup>88</sup> Directive 2001/37/EC, supra note 37, Article 1 and recital 4.

<sup>89</sup> *Ibid.*, recitals 11 and 34.

<sup>90</sup> S. Crosby, *The new Tobacco Control Directive: an illiberal and illegal disdain for the law*, supra note 6, p. 184.

<sup>91</sup> *Ibid.*

Indeed, the foregoing raises questions as to the limits of legislative competence, which the EU legislature must respect in course of adopting harmonising measures affecting public health. The following section discusses the issues concerning the, often blurred, limits of EU competence.

## 4.2 Limits to the Scope of Harmonisation

Albeit the principle of conferral *per se* is an undisputed concept constituting an inherent element in the general functioning of the Treaty, express and straightforward limits do not exist in all areas. In a number of sector-specific Treaty provisions the division of competences is clear, but this is not the case with Article 114 TFEU, which, as mentioned above, may be described as being functionally driven.<sup>92</sup>

The functionality results in the fact that, in principle, *any* national regulation can be harmonised by having recourse to Article 114 TFEU, on the condition that it contributes to the functioning of the internal market. This is to say that virtually nothing is on the face of it out of reach for the EU legislature to harmonise, with the exception of the explicit exclusions in Article 114(2) TFEU of fiscal harmonisation, harmonisation affecting free movement of persons and harmonisation of rights and interests of employed persons.<sup>93</sup>

As pointed out in previous chapter, the CJEU has established criteria for determining whether a harmonising measure may correctly be adopted under Article 114 TFEU. In practice, however, the EU legislature has not always confined themselves strictly to the aforementioned criteria. It has been pointed out that, outside those criteria, the legislature has in practice extended their actions to harmonise diverse national rules, so as to merely *facilitate* trade or to remove *uncertainty*.<sup>94</sup> Such extension, although not crucial on the face of it, raises severe concerns about the use of Article 114 TFEU as an *instrument of general governance*<sup>95</sup> – something to which it obviously was not designed. To that effect, the CJEU has held that judicial review of measures based on Article 114 TFEU would be rendered *nugatory*, if a *mere finding of disparities between national rules [...] were sufficient to justify the choice of Article [114 TFEU] as a legal basis*.<sup>96</sup>

However, even though Article 114 TFEU cannot be regarded as an instrument of general governance, the EU legislature has a wide margin of discretion in harmonising national provisions that are likely to fragment the internal market. As is evident, the dividing line is relatively thin, which is

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<sup>92</sup> S. Weatherill, *The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law has become a "Drafting Guide"*, German Law Journal, Vol. 12, No. 03, 2011, p. 831.

<sup>93</sup> *Ibid.*

<sup>94</sup> D. Wyatt, *Community Competence to Regulate the Internal Market*, supra note 55, p. 1.

<sup>95</sup> *Ibid.*

<sup>96</sup> Case C-376/98 *Tobacco Advertising I*, supra note 43, para 84.

highlighted well by Bernard. He makes a distinction between the concepts of the common *market* on one hand, and the *common* market on the other. Such minor difference in the emphasis of the wording opens two diverse interpretations of the concept. In this context, the common *market* refers to the *market in general*, whereas the *common* market refers to the creation of a *single, unified market*. The latter, geographically centred view has been more often adopted by the CJEU in their case law.<sup>97</sup>

In the absence of express division of competences, it is the role of the CJEU to ultimately interpret and set the limits to EU competence in a given area. The downside of this, however, is that in exercising their power of setting limits to regulatory competence, the CJEU simultaneously provides the EU legislature with a *drafting guide*.<sup>98</sup> According to Weatherill, the pattern is circular: *the Court presents a formula which defines the proper scope of legislative harmonisation [...], the EU legislature duly adopts the approved but reliably vague vocabulary and, provided the drafting is well-chosen, the Court has no plausible basis on which to set aside the legislative act.*<sup>99</sup> The foregoing further supports the finding that the secondary nature of express public health considerations in the Tobacco Products Directive is not merely incidental.

As mentioned in chapter 2, there have been also successful cases for challenging a measure's legal basis in Article 114 TFEU, such as *Tobacco Advertising I*. Next, it is relevant to move on to evaluate the main attempts to challenge the Tobacco Products Directive, and the ban on tobacco products for oral use, in particular.

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<sup>97</sup> N. Bernard, *The future of European economic law in the light of the principle of subsidiarity*, *Common Market Law Review*, 33, 1996, pp. 640-641. See also C. Barnard, *The Substantive Law of the EU – The Four Freedoms*, supra note 45, p. 612.

<sup>98</sup> S. Weatherill, *The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law has become a "Drafting Guide"*, supra note 92, p. 833.

<sup>99</sup> *Ibid.*, p. 828.

# 5 Challenging the Tobacco Products Directive

In numerous occasions, harmonisation based on what is now Article 114 TFEU has resulted in vast criticism. This is usually so where the EU has allegedly expanded their competence and acted *ultra vires* in an area falling within the competence of the Member States.<sup>100</sup> In that respect, the Tobacco Products Directive is not an exception. In *British American Tobacco*, the validity of the Directive in general was brought into question, while in *André* and *Swedish Match*, under scrutiny was Article 8 of the Directive and the marketing ban on tobacco products for oral use, specifically.

This chapter presents the judgments in the aforementioned cases, including the Opinions of AG Geelhoed. Analyses of the cases follow the respective CJEU's reasoning.

## 5.1 *British American Tobacco*

*British American Tobacco*<sup>101</sup> concerned tobacco product manufacturers, British American Tobacco and Imperial Tobacco (the claimants), who questioned the validity of the Tobacco Products Directive. Consequently, they sought a declaration from the UK national court that the UK could not exercise their powers of implementing the Directive. The national court submitted questions for preliminary ruling, the most relevant of which concerned the appropriateness of Article [114 TFEU] as the legal basis for the Directive, and alleged infringements of the principles of proportionality and subsidiarity.

### 5.1.1 Opinion of Advocate General Geelhoed

As to the appropriateness of the legal basis, the main issue was whether a measure intended to protect public health can be based on Article 114 TFEU. In his Opinion, AG Geelhoed started by emphasising that Article 114 TFEU does not grant the EU legislature a general power to harmonise national laws, but allows the EU to act where actual barriers have arisen or where barriers are likely to arise. The principal objective – protection of public health – of EU action is not, according to AG Geelhoed, important as long as the legitimate objective – contribution to the internal market – is sufficiently fulfilled. Furthermore, he did not accept the claimants' argument, according to which the EU legislature has wrongfully circumvented the express exclusion of harmonisation in the field of public

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<sup>100</sup> D. Slater, *The scope of EC harmonising powers revisited?*, supra note 57, p. 137.

<sup>101</sup> Case C-491/01 *British American Tobacco*, supra note 76.

health in Article [168(5) TFEU]. Referring to the intent in drafting the Maastricht Treaty and the complementary nature of Article 168 TFEU in relation to Article 114 TFEU, he noted that the EU has deliberately been given power to act within the area of public health. Therefore, inability of the EU to harmonise public health related matters under Article 114 TFEU would render that Article ineffective.<sup>102</sup>

As to the proportionality of the measure, AG Geelhoed pointed out that the main issue was whether the Directive was appropriate to achieve the objective of protecting public health and whether there were less intrusive means to achieve it. In that regard, he argued that the EU legislature had been successful in balancing between substantial, effective measures and the fact that tobacco consumption cannot be banned entirely. AG Geelhoed, therefore, found that the measure was appropriate and that he could not identify any less intrusive means of achieving the high level of public health protection.<sup>103</sup>

Finally, as to the principle of subsidiarity, AG Geelhoed merely noted that the CJEU should not go into an unduly detailed scrutiny thereof. He argued that in circumstances such as those in the proceedings, it is not difficult to confirm that the principle of subsidiarity is properly served. Action at the EU level was, he argued, necessary in view of the fact that the diverse national rules of the Member States were threatening to give rise to obstacles to trade.<sup>104</sup>

## 5.1.2 Judgment of the Court

As regards the use of Article 114 TFEU as the Directive's legal basis, the CJEU based their ruling on the premise of increasing public awareness on the dangers of tobacco consumption. Public awareness was likely to lead to the adoption of new, more stringent rules by the Member States reflecting such development, which would ultimately create obstacles to trade in the internal market. As to the removal of those potential obstacles, the CJEU referred to Article 13(1) of the Tobacco Products Directive, which seeks to ensure the free movement of tobacco products that comply with the minimum standards laid down by the Directive. It is this explicit free movement clause that, according to the CJEU, genuinely *gives the Directive its full effect in relation to its object of improving the conditions for the functioning of the internal market*. This being the case, the CJEU confirmed that the decisive nature of public health concerns could not render Article 114 TFEU an inappropriate legal basis for the Directive.<sup>105</sup>

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<sup>102</sup> Opinion of Advocate General Geelhoed in Case C-491/01 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd* [2002] ECR I-11453, paras 103-104, 108, 111 and 113-114.

<sup>103</sup> *Ibid.*, paras 230-231.

<sup>104</sup> *Ibid.*, para 285.

<sup>105</sup> Case C-491/01 *British American Tobacco*, *supra* note 76, paras 67, 74-75 and 99.

As to the relationship between Article 114(3) and 168(5) TFEU, the CJEU reminded that it is true that other Treaty articles may not be used as a legal basis to circumvent the explicit exclusion of EU competence to harmonise public health matters, as stipulated in Article 168(5) TFEU. However, the CJEU continued that the EU legislature cannot be prevented from harmonising in case the conditions of Article 114 TFEU are satisfied, and that it had not been established that the Directive decisively pursues *an end other than that of improving the conditions for the functioning of the internal market*.<sup>106</sup>

Furthermore, the CJEU did not accept the claimants' argument that the Directive seeks to achieve the alleged internal market aims in a disproportionate manner. The CJEU pointed out that the EU legislature must be entitled to *a broad discretion in an area [...] which entails political, economic and social choices [...] and in which it is called upon to undertake complex assessments*. That is, according to the CJEU, a measure such as the Tobacco Products Directive would be disproportionate only if it was *manifestly inappropriate* to pursue the desired objective. The threshold being so high, it is unsurprising that the CJEU found that the Directive is an appropriate means of pursuing both internal market and health protection objectives, and that it does not go beyond what is necessary to pursue them.<sup>107</sup>

Finally, the CJEU confirmed that the principle of subsidiarity does in fact apply where the EU legislature adopts harmonising measures on the basis of Article 114 TFEU, since that Article does not provide the legislature exclusive competence to act. However, in determining that the principle was properly served, the CJEU merely pointed out that the objective of eliminating obstacles created by diverse laws of the Member States whilst ensuring a high level of public health protection could only be achieved through EU-level action. In that regard, the CJEU referred to the fact that national laws regulating tobacco products had continued to develop in a heterogeneous manner prior to the adoption of the Tobacco Products Directive.<sup>108</sup>

To conclude, the CJEU upheld the validity of the Tobacco Products Directive. The judgment can be said to mark a retreat from the CJEU's previous case law, namely *Tobacco Advertising I* where the reasoning reflected *willingness to prevent over extensive recourse to Article [114 TFEU] by limiting its use to measures with a demonstrated positive effect on interstate trade*. The present judgment seems to undermine such development by placing emphasis on hypothetical future obstacles.<sup>109</sup>

One may also identify in the reasoning the difference of CJEU's approach between the *existence* and *exercise* of EU competence. The CJEU seems to

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<sup>106</sup> Ibid., paras 190-191.

<sup>107</sup> Ibid., paras 123 and 141.

<sup>108</sup> Ibid., paras 179 and 181-183.

<sup>109</sup> D. Slater, *The scope of EC harmonising powers revisited?*, supra note 57, p. 146.

adopt a strict approach when controlling the existence of EU competence. However, once such competence is acknowledged, the CJEU's *control over the exercise of this competence seems much more restrained*.<sup>110</sup>

Finally, the CJEU's reasoning as to the exclusion of harmonisation laid down in Article 168(5) is also interesting. Even though, as mentioned above, it is settled case law that a measure can be based on Article 114 TFEU irrespective of the fact that public health is a decisive factor thereof, the CJEU mentions that it had not been established that the Tobacco Products Directive pursued an end other than that of contribution to the internal market. Historically, this appears to be the first time for the CJEU to imply that the relationship between a measure's objectives can bear relevance on the choice of Article 114 TFEU as the legal basis, and consequently on the very existence of EU competence. Unfortunately, the CJEU does not develop their reasoning thereof.<sup>111</sup>

## 5.2 *André and Swedish Match*

*André*<sup>112</sup> and *Swedish Match*<sup>113</sup> were natural sequels for *British American Tobacco*, since the latter concerned the validity of the Tobacco Products Directive in general and, accordingly, the CJEU did not separately consider its most far-reaching provision: Article 8 prohibiting the sale of tobacco products for oral use.

In both *André* and *Swedish Match*, the claimants wished to place on the internal market tobacco products falling within the definition of tobacco for oral use as defined in Article 8 of the Tobacco Products Directive. The claimants challenged the respective marketing prohibitions imposed upon them claiming that Article 8 of the Directive was invalid. At issue was whether a total ban on a specific product could have Article [114 TFEU] as its legal basis. In addition, questions were raised as to the proportionality of the measure, as well as to issues relating to the principles of equal treatment and duty to give reasons.

### 5.2.1 Opinion of Advocate General Geelhoed

In his Opinion,<sup>114</sup> which covered both cases, AG Geelhoed recalled the inherent criteria for the use of Article 114 TFEU as a legal basis and found that the diverse development of national laws regulating tobacco products did create obstacles to the internal market. Such finding was evident since,

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<sup>110</sup> C. Hillion, *Tobacco Products in the Internal Market*, The Cambridge Law Journal, 63(2), 2004, p. 299.

<sup>111</sup> D. Slater, *The scope of EC harmonising powers revisited?*, supra note 57, p. 145.

<sup>112</sup> Judgment of the Court in Case C-434/02 *Arnold André GmbH & Co. KG v Landrat des Kreises Herford* [2004] ECR I-11825.

<sup>113</sup> Case C-210/03 *Swedish Match*, supra note 68.

<sup>114</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29.

he argues, although the Member States might have prohibited tobacco products for oral use independently, they would not necessarily have done it in a coordinated manner in case the EU-wide ban had been removed.<sup>115</sup>

As to the suitability of a ban adopted by relying on Article 114 TFEU, AG Geelhoed first acknowledged the rareness of a total ban as a means to contribute to the internal market. In that regard, he noted that express prohibitions on the marketing of specific products could not be found even in measures regulating narcotic drugs, psychotropic substances or explosives intended for civil use. However, he recalled that the EU legislature enjoys wide discretion in determining whether to choose regulating the lawful contents of specific products or imposing a total ban on their marketing.<sup>116</sup>

AG Geelhoed continued by stating that the ban could be considered to contribute to the conditions of the internal market, since the exclusion of tobacco products for oral use from the market results in diminished enforcement costs and less required efforts to control other smokeless tobacco products.<sup>117</sup> While such argument is self-evident when it comes to enforcement costs, the reduction in efforts to control other products appears to be unclear. It is hard to see how banning one particular product could reduce the actual efforts directed towards controlling other products. On the contrary, having regard to the relatively strict tobacco regulation in the EU, it might be unlikely for the EU to reduce efforts to control other smokeless tobacco products even if tobacco products for oral use were allowed to be marketed in the internal market.

AG Geelhoed emphasised that the ban affects only a certain category of tobacco products intended to be consumed in a specific manner, and that the scope of the ban does not, therefore, substantially differ from a prohibition to market tobacco products with certain contents. However, he did not find it necessary to develop the foregoing arguments, but merely recalled that the EU legislature is, in any event, competent to prohibit certain products under Article 114 TFEU.<sup>118</sup>

Referring to the requirement to ensure high level of health protection, AG Geelhoed pointed out that the cases concerned were particular in nature. Even though it was clear that the EU legislature pursues high level of health protection by banning tobacco products for oral use, it remained uncertain if the measure is actually appropriate and effective in such pursuit. He even noted that it is *conceivable that the policy goal would have been better served if the [Union] legislature had allowed the marketing of [tobacco products for oral use]*. However, when it came to scientific evidence on the health effects of tobacco products for oral use, AG Geelhoed found that the threshold for upholding restrictive measures is lower than that of removing

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<sup>115</sup> Ibid., paras 65-66.

<sup>116</sup> Ibid., paras 68, 71 and 77.

<sup>117</sup> Ibid., para 79.

<sup>118</sup> Ibid., paras 82-83.

them. As long as serious indications on the health risks of tobacco products for oral use exist, the EU is, in principle, allowed to restrict the marketing of certain products for the purposes of protecting public health.<sup>119</sup>

Moreover, AG Geelhoed noted that the scientific uncertainty does not only concern the prohibited product, but also – or even predominantly – expectations about consumer behaviour. In such context, he considered whether the ban could have been based on the precautionary principle, according to which the EU legislature may take precautionary action if there is scientific uncertainty about realistic risks implying substantial public interest consequences. Interestingly, AG Geelhoed denied the possibility to rely on the precautionary principle due to the fact that the uncertainty was created by expectations about consumer behaviour, and that substantial damage to public health was not plausible if tobacco products for oral use appeared on the internal market.<sup>120</sup>

However and even more interestingly, having ruled out the precautionary principle, AG Geelhoed turned to consider the principle of preventive action, and found that the EU legislature had correctly taken preventive action against the potential *irreversible effects* resulting from the placing of tobacco products for oral use on the internal market in free circulation.<sup>121</sup> The reliance on the principle of preventive action separately from the precautionary principle may be considered unusual, since the CJEU has not always differentiated between them. Indeed, the CJEU has usually either dealt with the two principles together or only dealt with the precautionary principle without expressly mentioning it.<sup>122</sup>

As to the proportionality of the ban, AG Geelhoed repeated the CJEU's reasoning in *British American Tobacco*, and recalled that the broad discretion enjoyed by the EU legislature in matters concerning complex political, economic and social choices resulted in the fact that it is hard to annul a measure on grounds of its disproportionate nature. To that effect and referring to the principle of preventive action, he noted that the ban was an appropriate measure, and that the EU legislature did not make a manifestly incorrect assessment in those circumstances. As to the effectiveness of the ban as a means of pursuing the desired policy objective, AG Geelhoed pointed out that other, less restrictive means would not have been equally effective in such pursuit.<sup>123</sup>

Furthermore, AG Geelhoed did not accept the claimants' argument, according to which the ban was in breach of the principle of equal treatment in that equivalent products are not subject to the ban and remain in free

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<sup>119</sup> Ibid., paras 88 and 94.

<sup>120</sup> Ibid., paras 95, 103 and 107.

<sup>121</sup> Ibid., paras 109-110.

<sup>122</sup> A. Alemanno, *The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Uncertainty*, Bocconi Legal Studies Research Paper No. 1007404, 2007, p. 6.

<sup>123</sup> Opinion of AG Geelhoed in Case C-434/02 *André*, supra note 29, paras 111-112, 115 and 117.

circulation. Having first admitted that similar products, indeed, have escaped the prohibition, he argued that the difference in treatment is not based on the characteristics of the products, but on the difference in their potential user groups.<sup>124</sup>

Finally, AG Geelhoed turned to consider the duty to give reasons established in Article [296 TFEU]. He referred to the absence of explicit reasons in the Tobacco Products Directive for maintaining the ban, and reminded that if a measure departs from usual practice – as an outright ban with an exception usually does – the EU legislature is obliged to give reasons that are even more detailed. Similarly, a more detailed reasoning is required in case of substantial changes in the context in which the measure is to operate. AG Geelhoed pointed out that the accession of Sweden to the EU and the derogation of Sweden from the effects of Article 8 of the Directive created disturbances in the functioning of the internal market of tobacco products, or more correctly, separated one market from the internal market. He argued that such division of the market goes against the fundamental concept of internal market as a whole, and that in those circumstances the confirmation of the ban could not be considered a *mere continuation of existing policy*.<sup>125</sup>

Consequently, AG Geelhoed found that the Tobacco Products Directive had failed to give adequate reasons for maintaining the ban, and suggested that Article 8 of the Directive should be declared invalid. However, he emphasised the need to maintain the effects of the ban in force, until a new provision with proper reasoning would be introduced.<sup>126</sup>

## 5.2.2 Judgments of the Court

In spite of the fact that the CJEU did not join the cases but ruled on each of them separately, the two judgments are presented as a single entity below due to the identical nature of their legal substance as well as their wording.

As to the suitability of Article 114 TFEU as the legal basis of the EU-wide ban on tobacco products for oral use, the CJEU ruled that the existence of obstacles to the free movement of certain products created by diverse national laws of the Member States, in principle, authorises the EU legislature to adopt measures under that Article. Such measures may, depending on the specific circumstances, amount to a prohibition to market those products. In course of action, however, the legislature must comply with the recognised legal principles laid down in the Treaty, such as the principle of proportionality.<sup>127</sup>

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<sup>124</sup> Ibid., para 127.

<sup>125</sup> Ibid., paras 134, 136-137, 140-141 and 146.

<sup>126</sup> Ibid., paras 150-151.

<sup>127</sup> Case C-434/02 *André*, supra note 112, paras 34-35. Case C-210/03 *Swedish Match*, supra note 68, paras 33-34.

The CJEU emphasised the fact that the prohibition in Article 8 of the Tobacco Products Directive is a mere reproduction of the original ban established in the preceding Directive. In that regard, the CJEU referred to the marketing bans adopted by three Member States at the time, which were likely to lead to a heterogeneous development of the market for the products concerned. As a supporting element in such development, the CJEU noted the growing public awareness of adverse health effects of tobacco products. The unique nature of the market for tobacco products for oral use resulting from Sweden's derogation could not, according to the CJEU, affect the legal assessment, since Sweden is simultaneously required to ensure that those products do not end up in circulation in the internal market. Consequently, the CJEU found that the EU legislature was entitled to adopt the ban in Article 8 of the Directive by having recourse to Article 114 TFEU.<sup>128</sup>

As to the proportionality of the ban, the CJEU reminded of the EU legislature's broad discretion in an area such as that concerned. This discretion may be questioned only if the adopted measure is manifestly inappropriate in pursuing its objective. In finding that the measure was not inappropriate, the CJEU referred to the recitals of the preceding Directive, in which it was stated that a complete ban was the only appropriate measure for the pursuit of high level of health and consumer protection.<sup>129</sup>

Turning to the development of scientific information, the CJEU pointed out that at the time of the Tobacco Products Directive's adoption, such development did not provide undisputed grounds for concluding that tobacco products for oral use did not present any danger to health, or that the dangers were inferior to those of other tobacco products. On the contrary, the CJEU focused on the mere fact that those products presented a risk to health. On these grounds, the CJEU concluded that proper attention had been paid to the development of scientific information.<sup>130</sup>

Moreover and contrary to the findings of AG Geelhoed, the CJEU ruled that the marketing prohibition complies with the duty to give adequate reasons. To that effect, the CJEU noted that the circumstances such as the novelty of the product on the internal market, their attractive nature to young people, in particular, and the diverse national laws of the Member States were similar to those of the time when the preceding Directive was adopted. Furthermore, the CJEU disregarded the traditional nature of tobacco products for oral use by finding that the Swedish territory, where such tradition exists, cannot be included in the assessment of the market for those products within the meaning of Article 8 of the Tobacco Products Directive due to the derogation enjoyed by Sweden under the Act of Accession.<sup>131</sup>

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<sup>128</sup> Case C-434/02 *André*, supra note 112, paras 37-42. Case C-210/03 *Swedish Match*, supra note 68, paras 36-41.

<sup>129</sup> Case C-434/02 *André*, paras 46-47. Case C-210/03 *Swedish Match*, paras 48-49.

<sup>130</sup> Case C-434/02 *André*, paras 49 and 51-52. Case C-210/03 *Swedish Match*, paras 51 and 53-54.

<sup>131</sup> Case C-434/02 *André*, paras 65-67. Case C-210/03 *Swedish Match*, paras 65-67.

Finally, the CJEU concluded that the marketing prohibition is not in breach of the principle of non-discrimination, since tobacco products for oral use were new to the internal market at the time of the adoption of the ban. The novelty of those products, according to the CJEU, resulted in the fact that the prohibited tobacco products for oral use were not in a similar situation as other smokeless tobacco products, which for one justifies the difference in their treatment.<sup>132</sup>

As a result, the CJEU upheld the validity of the prohibition to market tobacco products for oral use. However, the judgment has been criticised for being inadequate and unsatisfactory. To start with, the reasoning is unconvincing as to the finding that the ban is an appropriate means of contributing to the internal market. It is difficult to see how the removal of a product that would potentially be marketed in some of the Member States can contribute to the functioning of the internal market.<sup>133</sup> It is undisputed that the CJEU correctly emphasised the importance of a connection between legislative harmonisation and the functioning of the internal market, but it has been argued that it takes *a rather wide view of the circumstances in which that connection may be established*.<sup>134</sup>

Furthermore, the CJEU's reasoning on the proportionality of a total ban as a means of pursuing its objective, in particular, deviated from their traditional jurisprudence. Because of the extensive emphasis on public health grounds, one might argue that the CJEU *almost impairs the general principles of law that it has previously guaranteed*.<sup>135</sup> The broad margin of discretion enjoyed by the EU legislature in a free movement context is also remarkable. The threshold of *manifestly inappropriate* required for invalidating a measure as disproportionate is significantly higher than that of the traditional proportionality test applied to situations where a Member State, for example, has allegedly restricted free movement of goods on public health grounds.

Moreover, it has been argued that the ban would be more understandable if it was adopted as a part of a wider regulatory scheme affecting a variety of tobacco products. However, in the absence of explicit reference, in the judgment or in the Directive, to the existence of such scheme, it can be said that the ban on a freestanding product conflicts with the CJEU's previous case law.<sup>136</sup> Indeed, in *Tobacco Advertising I*, the CJEU held that the

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<sup>132</sup> Case C-434/02 *André*, supra note 112, para 69. Case C-210/03 *Swedish Match*, supra note 68, para 71.

<sup>133</sup> T. Konstadinides, *Division of Powers in European Union Law: The Delimitation of Internal Competence Between the EU and the Member States*, Kluwer Law International, 2009, pp. 199-200.

<sup>134</sup> S. Weatherill, *Current Developments: European Law – Free Movement of Goods*, International and Comparative Law Quarterly, 55(2), 2006, p. 464.

<sup>135</sup> T. Konstadinides, *Division of Powers in European Union Law: The Delimitation of Internal Competence Between the EU and the Member States*, supra note 133, pp. 199-200.

<sup>136</sup> S. Weatherill, *The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law has become a "Drafting Guide"*, supra note 92, p. 836.

prohibition of advertising in certain freestanding categories of items did in no way contribute to functioning of the internal market.<sup>137</sup>

Finally, the judgment can be said to undermine the principle of subsidiarity. Having regard to the fact that the ban is not intended to apply equally throughout the EU due to the derogation enjoyed by Sweden, it is conceivable that the objective actually could have been achieved at the Member State level. As a general remark, one could argue that the principle of subsidiarity, when circumvented as lightly as in the cases at hand, seems to be ill-suited means of challenging the EU legislature's attempts to extend their competences with a free movement disguise.<sup>138</sup>

As the validity of the Tobacco Products Directive and the prohibition to market tobacco products for oral use has been confirmed by the CJEU, it remains in force with all its content. Be it as it may, the Directive is currently going through a revision, which is the subject of examination in the following chapter.

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<sup>137</sup> Case C-376/98 *Germany v Parliament and Council*, supra note 43, para 99.

<sup>138</sup> T. Konstadinides, *Division of Powers in European Union Law: The Delimitation of Internal Competence Between the EU and the Member States*, supra note 133, pp. 200 and 202.

# 6 Revision of the Tobacco Products Directive

The EU legislature is currently in progress of revising the Tobacco Products Directive. As part of the preparatory procedure, Directorate General for Health and Consumers (DG SANCO) has publicly consulted affected stakeholders about the need for the revision, as well as the potential policy options. In course of the consultation, stakeholders had the opportunity to present their arguments in all relevant areas relating to the substance of the revision. One of such areas concerns smokeless tobacco products, including tobacco products for oral use.<sup>139</sup>

Sweden, as the sole Member State enjoying an exception from the ban on the marketing of tobacco products for oral use, has naturally strong interests in lifting the ban. Not only would it extend the current market to a new European level economically, but also reflect a remarkable political milestone following the almost 25-year period of EU-wide prohibition.

This chapter evaluates the findings of the recent public consultation by DG SANCO relating to the revision of the Tobacco Products Directive, presents Sweden's approach to the marketing ban, and assesses the potential future development of the respective legislation.

## 6.1 Public Consultation

According to the consultation, the majority of Member States support maintaining the ban on tobacco products for oral use and are in favour of extending the ban to cover all types of smokeless tobacco products, mainly due to concerns about their harmful effects on health. Unsurprisingly, one Member State presented *particularly strong interest* in lifting the ban on grounds that *it is illogical for [tobacco products for oral use] to be the only tobacco product prohibited within EU without scientific evidence to treat it any differently than other tobacco products.*<sup>140</sup>

Public health organisations would maintain the ban since, without convincing predictions on how tobacco products for oral use would be perceived in the internal market, the introduction of a *dangerous product* to the market has no legitimate reasons. Some other non-governmental organisations argue that there is sufficient scientific information to conclude that tobacco products for oral use are less harmful than cigarettes and other tobacco products, and could partly replace the use of cigarettes.<sup>141</sup>

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<sup>139</sup> Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC), DG SANCO, 2011, pp. 4-5.

<sup>140</sup> *Ibid.*, p. 11.

<sup>141</sup> *Ibid.*, p. 12.

A great majority of tobacco industry representatives suggested lifting the ban on tobacco products for oral use. Two distinct grounds thereof can be found, the first of which is the potential substitutive effect, and the second that by maintaining the ban the EU is *effectively blocking the industry from developing other forms of products which are less harmful than cigarettes*. Respondents from the smokeless tobacco industry contend that there is *universal consumer demand to lift the ban* and that without proper scientific base the ban should be lifted.<sup>142</sup>

In addition, a vast majority of citizens are in favour of lifting the ban on tobacco products for oral use. They point to the apparent less harmful health effects of smokeless tobacco products compared with those of cigarettes. Moreover, a part of respondents highlights the importance of consumer's freedom of choice. To that effect, Crosby has also presented criticism for the present state of regulation. He claims that the CJEU has previously considered the *average consumer* reasonably well informed and observant, but by banning a product the EU legislature implies that the average citizen is *uneducated, unable to read, unaware of the world around him, and unable to decide what is good or bad for him*.<sup>143</sup>

Overall, the results seem to propose that the ban on tobacco products for oral use divides the opinions between the majority of Member States' officials and public health promoting organisations on one hand, and the industry and EU citizens on the other. Bearing in mind the exceptional structure of the market for tobacco products for oral use, it is pertinent to have due regard to the official position of Sweden in the following section.

## 6.2 Swedish Standpoint

Swedish Government has sought to include tobacco products for oral use in the European uniform tobacco regulation, which currently exists as regards cigarettes, for example. To that effect, Sweden has pointed out that hazardous substances and additives can be regulated in a uniform manner for all tobacco products, which for one would genuinely serve the principle of free movement of goods as well as public health aims.<sup>144</sup> In practice, this would mean that tobacco products for oral use would, similarly to other tobacco products, be regulated as to their lawful contents instead of their intended way of use.

In addition to a uniform content related regulation, Sweden urges to lift the ban on grounds of lacking scientific evidence showing that tobacco products for oral use are more harmful than other smokeless tobacco products. Thus, as long as such evidence does not exist to an appropriate extent, there is no

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<sup>142</sup> Ibid.

<sup>143</sup> Ibid., p. 13. S. Crosby, *The new Tobacco Control Directive: an illiberal and illegal disdain for the law*, supra note 6, p. 187.

<sup>144</sup> Swedish Ministry for Foreign Affairs – The Internal Market of the European Union – Snus, available at <http://www.sweden.gov.se/sb/d/9625/a/157533>, accessed on 3 May 2012.

reason to treat tobacco for oral use differently from other smokeless tobacco products, which are currently in free circulation in the internal market.<sup>145</sup>

Finally, Swedish Government is of the opinion that the marketing prohibition is discriminatory and disproportionate. Referring to recent scientific studies conducted by WHO and SCENIHR, Sweden points out that the original grounds for the marketing ban do not comply with the principle of non-discrimination. Moreover, it is argued that the current level of health and consumer protection can be achieved by adopting less restrictive measures than a complete ban on a single freestanding product.<sup>146</sup> As an alternative, Sweden suggests adopting a measure based on *uniform and responsible regulation of all tobacco products*,<sup>147</sup> which would undoubtedly be less restrictive means of pursuing health protection aims. Consequently, Sweden argues that the Tobacco Products Directive, as it now stands, does not reflect recent scientific development or contribute to the functioning of the internal market.<sup>148</sup>

Having presented the results of the public consultation and the approach adopted by Sweden it is relevant to turn to the analysis of the potential effects of the current revision of the Tobacco Products Directive to future tobacco regulation.

## 6.3 Outlook

The rationale for the revision originates from *new international, scientific and market developments*, which *require reflecting whether the Directive still fully guarantees its original objectives*, such objectives being the facilitation of the functioning of the internal market in tobacco products and simultaneously ensuring a high level of health and consumer protection.<sup>149</sup>

In the present absence of a draft proposal of the Directive under revision, the following analysis concentrates on the measures envisaged by the reform. Currently, the anticipated reforms include the harmonisation of packaging requirements and a ban on visual displays for tobacco products. Harmonisation of packaging requirements is likely to prohibit *logos, colors, brand images, and promotional elements on packaging*. Brand names are likely to remain allowed, but they must be presented in a *mandated size, font and place*. The visual display ban would prohibit *the display of tobacco*

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<sup>145</sup> Swedish Government Offices Memorandum, *Revision of the Tobacco Products Directive: Smokeless tobacco products and tobacco for oral use*, 22 February 2011, p. 1.

<sup>146</sup> *Ibid.*, pp. 1-2.

<sup>147</sup> Swedish Government Offices, Ministry for Foreign Affairs, *Uniform and responsible regulation of all tobacco products*, 14 July 2011.

<sup>148</sup> Swedish Government Offices Memorandum, *supra* note 145, p. 2.

<sup>149</sup> A. Alemanno, *Out of Sight Out of Mind – Towards a New EU Tobacco Products Directive*, *Columbia Journal of European Law*, 18(2), 2012, p. 6.

*products at points of sale.* Thus, the revision is likely to endeavour going further than the minimum conditions laid down in the FCTC require.<sup>150</sup>

The main issue inherent in the revision is likely to be, once again, that of the EU legislature's competence in adopting such EU-wide schemes. A lot will depend on the choice of the legal basis for the upcoming revision.<sup>151</sup> However, the historical tendency of secondary legislation on tobacco products to be based on Article 114 TFEU and the explicit exclusion of harmonisation relating to public health in matters concerning tobacco in Article 168(5) TFEU would suggest the former, especially if one bears in mind that the CJEU has upheld the validity of the present Directive in previous occasions.

Considering the intended revision of packaging requirements and visual display ban in light of the previous Directive, the former does not seem to differ in substance from the present packaging requirements. If one recalls that, similarly, packaging requirements were tightened during the adoption of the Tobacco Products Directive and subsequently confirmed by the CJEU, it seems likely for the packaging revision to pass. However, the difference is the fact that the currently envisaged revision may go beyond what is necessary, with a particular emphasis on the presentation of brand names. In concluding that the visual display ban is likely to succeed, it suffices to note that in Finland, for example, such ban is already in force. Following the rationale of adopting the ban on tobacco products for oral use, the fact that one or more Member States are contemplating to adopt similar measures can justify the EU-level interference in the form of harmonisation.<sup>152</sup>

When it comes to tobacco products for oral use, specifically, it can be noted that the industry attempts to lift the ban seem to continue. It is likely that an overall review of the ban becomes timely during the Tobacco Products Directive's revision process. Other signs pointing at the potential need for a review include the current spread of non-smoking legislation throughout Europe, which potentially encourages consumers to quit smoking. In order to maintain their market share, the industry representatives are therefore likely to increase their urge in lifting the ban. Finally, public health experts have suggested that tobacco products for oral use may *play a key role in tobacco control strategies by acting as a lower risk source of nicotine* for consumers of cigarettes.<sup>153</sup>

However, the recent review of smokeless tobacco products and their health effects, in particular, by SCENIHR continues to recognise the addictive nature of smokeless tobacco products, as well as their health risks. This may

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<sup>150</sup> Ibid., pp. 2 and 6.

<sup>151</sup> Ibid., p. 13.

<sup>152</sup> Ibid., pp. 23-24.

<sup>153</sup> M. McKee et al, *Public Health Policies* in E. Mossialos et al, *Health Systems Governance in Europe: the role of EU law and policy*, supra note 39, pp. 268-269.

suggest that the ban is unlikely to be lifted in the near future.<sup>154</sup> On the other hand, as mentioned in the previous section, also Sweden relies in their arguments on the SCENIHR results in their pursuit towards lifting the ban. This is an excellent indication of the fact that, ultimately, it all comes down to questions of interpretation.

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<sup>154</sup> Ibid., p.268.

## 7 Conclusion

This thesis has shown that, contrary to the requirements of Article 114 TFEU as the Tobacco Products Directive's legal basis, the marketing prohibition of tobacco products for oral use does not seem to contribute to the functioning of the internal market. Instead of contributing to the internal market, the ban can be considered to partition the market for tobacco products for oral use, and prevent that market from developing in the first place. Moreover, the prohibition appears to pursue predominantly health and consumer protection objectives, due to which it seems to be ill-suited to be based on Article 114 TFEU. It is not disputed that the EU must be competent to harmonise tobacco product regulation, but such harmonisation has to have a genuine free movement objective, as required by Article 114 TFEU.

In addition, the EU legislature is, in adopting and revising harmonising measures on the basis of Article 114 TFEU, obliged to take into account the development of scientific facts. The thesis has suggested that such obligation has been overlooked in the context of transferring the ban to the Tobacco Products Directive. This view is supported by the fact that, originally, the Directive establishing the ban referred to, at the time recent, scientific evidence on the adverse health effects of tobacco products for oral use as a substantive factor in justifying it.

Furthermore, it has been established that the Tobacco Products Directive seems to circumvent the explicit exclusion of EU competence in public health matters laid down in Article 168 TFEU. The approach taken by the CJEU, according to which it is possible for the EU legislature to adopt, on the basis of Article 114 TFEU, measures with the primary aim of harmonising public health related issues results in an unsustainable legal situation. The complementary role of the EU in issues relating to public health seems, as regards the regulation of tobacco products for oral use, to have evolved into a complete one.

The role of the CJEU in setting limits to the competence enjoyed by the EU legislature has proven to be problematic. The reasoning by the CJEU in the most relevant case law has been unsatisfactory when it comes to issues such as proportionality of a total ban as a means of pursuing the alleged internal market objectives. The establishment of a total ban is the most restrictive measure limiting the free movement of goods, especially when other, less restrictive means are available. Such means include the uniform and responsible tobacco products regulation, as suggested by Sweden, where tobacco products for oral use would be regulated as to their labelling and lawful contents, as is the case with other tobacco products. It has also been shown that the CJEU has failed to have due regard to the proper application of the principle of subsidiarity. It has been argued that the decision on the

marketing of tobacco products for oral use could have been left for the individual Member States to make.

Finally, the thesis has established that the political pressure for lifting the ban on tobacco products for oral use is likely to continue in course of the currently on-going revision of the Tobacco Products Directive, during which the EU legislature is, in principle, obliged to review the marketing prohibition. The rapid development of European non-smoking legislation and tightening of tobacco products regulation, in general, is likely to open a possibility for tobacco industry to further pursue lifting the ban on smokeless tobacco products for oral use as a potentially less harmful alternative to other tobacco products, such as cigarettes.

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