

Legal Opinion

This legal opinion relates to the interpretation of article 15 of the tobacco directive of the European Parliament and the Council of 3 April 2014¹ and its relationship with article 8 of the Protocol to eliminate illicit trade in tobacco products², adopted in Seoul on 12 November 2012.

In particular, this legal opinion is meant to determine whether article 8 of the protocol binds in any way the European Union member states when they transpose the Directive into domestic law.

The Seoul protocol was adopted following the World Health Organization Framework Convention on Tobacco Control, adopted in Geneva on 21 May 2003³.

The framework convention entered into force internationally on 27 February 2005, it binds internationally the European Union as of 30 June 2005⁴ and has been integral part of EU law since then⁵.

The Union signed the Protocol on 20 December 2013, before the adoption of the directive and sent its instrument of formal confirmation on 24 June 2016, after the adoption of the directive. It has been ratified by 5 member states: Austria, Spain, France, Latvia and Portugal. Pursuant to article 44 of the Protocol, the Union made a declaration concerning the allocation of competences between itself and its member States⁶. The protocol has not entered into force in the international legal order, since it has not yet gathered the forty ratifications necessary for that purpose. In the absence of international entry into force, the protocol is not yet integral part of the Union's law, despite its instrument of formal confirmation of 24 June 2016. (Nevertheless, states that have ratified it can implement it)

The directive was adopted notably in order to abide by the framework convention obligations⁷. Its validity was confirmed by the European Court of Justice⁸; it must be transposed by 20 May

¹ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member states concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC

² <http://www.who.int/fctc/protocol/en/>

³ http://www.who.int/fctc/text_download/en/

⁴ https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=_en

⁵ Case 181/73, *Haegeman*, 30 April 1974, §§4-5 ; C-344/04, *IATA*, 10 January 2006, §36

⁶ https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4-a&chapter=9&lang=fr&clang=_fr#EndDec

⁷ Directive, Recital 7 and Article 1 *in fine*.

⁸ Judgments of 4 May 2016 in Cases C-358/14 *Poland v European Parliament and Council of the European Union*, C-477/14 *Pillbox 38 (UK) Limited v Secretary of State for Health and Philip Morris Brands SARL and others v Secretary of State for Health*.

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2016⁹. The Commission is empowered to adopt implementing¹⁰ and delegated acts¹¹, notably as regards the elements mentioned in article 15, paragraph 12. The provisions regarding track and trace “shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024”¹².

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Articles 15 of the directive and 8 of the protocol both regulate track and trace of tobacco products placed on the market.

While article 8, paragraph 12, of the protocol reads that obligations as regards track and trace “shall not be performed by or delegated to the tobacco industry”, article 15 of the directive does not contain, *expressis verbis*, any similar prohibition and only provides in its paragraph 8 that the relevant data as regards track and trace must be stored by an independent third party with whom the manufacturers and importers of tobacco products conclude data storage contracts for that purpose.

This difference between the two texts raises the question of how, as a matter of the European Union law, Member states can, or must, transpose the directive.

The present legal opinion considers that the directive does not compel member states to entrust the tobacco industry with the track and trace of tobacco products (I) and that, even if it seems to allow member states to do so (II), its correct interpretation leads to consider that it is prohibited to adopt transposition measures allowing them to do so (III).

I. No obligation to entrust the tobacco industry with tobacco track and trace

First of all, it is a certainty that the directive does not compel member states to entrust track and trace operations – particularly affixing the unique identifier to each tobacco products’ unitary packet – to the manufacturers and importers of these products. Indeed, there is no such provision in the directive. If its text did impose such an obligation, it would obviously be contrary to the protocol. Of course, formally, the protocol did not limit the European regulator’s freedom at the time of the adoption of the directive insofar as it did not bind the Union (yet). However, it must be reminded that the Union signed the protocol before it adopted the directive, so that it is bound by a minimum good faith obligation to “refrain from acts which would defeat the object and purpose of a treaty”: codified under article 18 of the Vienna convention on the law

⁹ Directive, article 29.

¹⁰ Directive, article 25.

¹¹ Directive, article 27.

¹² Directive, art. 15 § 13.

of treaties, this obligation being considered as international customary law and as corollary, in international public law, to the principle of protection of legitimate expectation in the community legal order¹³.

Therefore, it appears that national transposition measures excluding the tobacco industry from track and trace operations, particularly in entrusting the affixing of the unique identifier to a public authority or to an independent third party controlled by a public authority, cannot be considered as contrary to the directive since it does not compel member states to entrust these operations to the tobacco industry.

II. Permission to entrust the track and trace operations to the tobacco industry?

Insofar as it does not compel member states to entrust track and trace operations to the tobacco industry, does the directive allow it? Many arguments can be put forward to affirm that member states have this freedom on the grounds of the directive and that they should exercise it this way:

- a) The directive does not prohibit member states to entrust track and trace operations to the industry, while it only requires them to “ensure that all unit packets of tobacco products are marked with a unique identifier”¹⁴, without mentioning who should affix the identifier.
- b) The directive imposes member states to ensure “that the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph 8.”¹⁵

¹³ T-115/94, *Opel Austria*, 22 January 1997, §94: therefore, « economic operators can rely on the principle of legitimate expectation to oppose the adoption, by the institutions, during the period before the entry into force of this international agreement, of any act contrary to the provisions of the said agreement which, after its entry into force, have direct effect on their legal situation.”

By virtue of the same principle of legitimate expectation deriving from the good faith principle of article 18 of the Vienna Convention on the law of treaties, a member state cannot claim that an international agreement, concluded with other member states and the Commission, and aiming to share the construction costs of a diplomatic building in Abuja, was not ratified in order to oppose the debt and to a financial compensation measure imposed by the Commission as soon as this state did not clearly express its intention not to participate to this common project anymore (T-231/04, *Greece v Commission*, 17 January 2007, §§85-104).,

¹⁴ Directive, article 15 §1.

¹⁵ Directive, article 15 §8.

According to the directive, the tobacco industry must provide the necessary equipment to ensure the track and trace of tobacco products to all intermediaries of the supply chain at its own cost. Therefore, it could be argued that the tobacco industry is tasked to affix the unique identifier since it is tasked to provide the equipment necessary to exploit the information: having to purchase and provide the equipment to read the unique identifier, the industry would be entitled to choose this equipment, as well as the identifier, and to affix it.

- c) The directive imposes member states to ensure that the tobacco industry concludes a service contract with an independent third party in order to store the data generated by the use of the equipment enabling the reading of the information contained in the unique identifier.¹⁶ Therefore, it can be affirmed that the track and trace system would be perfectly robust and secure, so that the manufacturers could be entrusted with the affixing of the unique identifier. This would be even reinforced by the fact that data storage is the only operation that is prevented from being entrusted to the tobacco industry on the grounds of the directive: *a contrario*, and considering the absence of such specific mention in the directive regarding any other track and trace operation, member states would be free to entrust the tobacco industry with any other operation and, considering the silence of the directive on that matter, it would be logical that it be this way.
- d) The preparatory documents show that the more restrictive positions of the European Parliament, referring to the Seoul protocol, have finally not been retained by the Union regulator following the trilogues.¹⁷

III. The prohibition to entrust the track and trace operations to the tobacco industry

None of the above arguments are convincing.

- a) If the directive does not expressly prohibit to entrust the affixing of the unique identifier to the tobacco industry, article 15 paragraph 1 nevertheless imposes upon member states an obligation to achieve a result: it consists in ensuring that “all unit packets of tobacco products are marked with a unique identifier”. In other words, national transposition measures creating the risk that certain unit packets would not bear such an identifier, must be considered as contrary to the member states’ obligation resulting from the directive. If affixing of the unique identifier is an operation entrusted to the tobacco industry, nothing guarantees that *all* unit packets will bear one. In that sense,

¹⁶ Directive, article 15, §8.

¹⁷ See the procedural file 2012/0366(COD),

<http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0366>

article 15 paragraph 1 can reasonably be interpreted as excluding a unique identifier's affixing method with the industry's intervention.

- b) The deduction proceeding from the second argument is not necessary. Indeed, it is perfectly possible to impose to the tobacco industry to provide the equipment necessary for the exploitation of the unique identifier, without making it responsible for its affixing. Since it falls on the Commission to determine through implementing acts the tracking and tracing systems' technical standards¹⁸, the tobacco industry will not have an unlimited choice as to the equipment to be provided to the intermediaries for the exploitation of the unique identifier and the generation of the data transmitted and collected by the independent third party. Without having the freedom to choose the track and trace technology, the industry cannot argue that it has to provide the track and trace equipment to the intermediaries of the supply chain in order to affirm that it should logically be entrusted with the initial operation enabling track and trace.
- c) It cannot be deducted from the specific obligation imposed on member states to ensure that manufacturers and importers of tobacco products must conclude data storage contracts with independent third parties that all operations of track and trace could be entrusted to the tobacco industry. Even if the *a contrario* argument appears logical, it does not impose itself on the grounds of article 15 read as a whole. Indeed, data storage is the ultimate link in the track and trace chain, so that its effectiveness relies on the transmitted data: it is useless to entrust an independent third party with track and trace data storage if the generation of this data for each unit is not perfectly ensured. Considering the reality of tobacco products' trade, storing incomplete data does not allow to comply with the objectives of article 15. What point is there in tasking an independent third party with the storage of data which carry the risk of being partial, since the industry is entrusted to affix the unique identifiers? The obligation to task an independent third party with the data storage is made compulsory in order to ensure that the industry does not tamper or erase the data. This would be useless if the data could fail to exactly reflect the reality of tobacco products' trade since, on the upper stream, each unit packet would not generate data. Far from meaning, *a contrario*, that all track and trace operations can be entrusted to the tobacco industry, the obligation to ensure that data storage is undertaken by an independent third party must be understood as meaning that member states are compelled to ensure the integrity of such data on the upper stream, and their comprehensiveness with regard to the reality of the tobacco products' trade.
- d) The argument deducted from the preparatory documents cannot succeed: "indeed, according to settled case-law, in the absence of preparatory documents expressing clearly the intention of the authors of a provision, it should only be relied upon the scope of the text, as the time of drafting, and confer the meaning that flows from its literal and logical interpretation (see, in that sense, case of 1 June 1961, *Simon v*

¹⁸ Directive, article 15, § 11.

European Court of Justice, 15/60, *Rec.* p. 223, 244; case from Tribunal of 14 December 2006, *André v Commission*, F-10/06, *RecFP* p. I-A-1-183 and II-A-1-755, point 44)¹⁹. It should also be noted, according to Advocate general Kokott, that the directive was adopted “following tough negotiations and an extremely animated legislative procedure”.²⁰ It is therefore necessary to stick to the text of the directive, its preparatory documents being irrelevant to interpret it.

Moreover, as the European Court of Justice reminded it in a judgment of 4 May 2016 which confirmed the validity of the directive, “The Court has consistently held that, if the wording of secondary law is open to more than one interpretation, preference should be given to the interpretation which renders the provision consistent with the Treaty rather than to the interpretation which leads to its being incompatible with the Treaty (see, inter alia, judgment in *Ordre des barreaux francophones et germanophone and Others*, C-305/05, EU:C:2007:383, paragraph 28).”²¹ Yet, article 168 of the Treaty on the Functioning of the European Union (TFEU) imposes that a “high level of human health protection [...] be ensured in the definition and implementation of all Union policies and activities.”

Considering that tobacco products’ track and trace is indispensable to tackle such products’ illicit trade, that illicit trade undermines the efforts put into the struggle against tobacco prevalence, policy which is part of the protection of human health, the interpretation of the directive in a way that would leave member states free to entrust the tobacco industry with all the track and trace operations excluding data storage would not be consistent with the objectives of the Treaty aiming to ensure a high level of protection of human health. Indeed, such involvement of the tobacco industry bears the risk that track and trace would not be thorough, and would reduce the level of protection of human health which could otherwise be attained. Thus, article 168 TFEU imposes to retain another interpretation of the directive that prohibits member states to entrust the tobacco industry with any operations as regards track and trace.

Finally, still “according to settled case-law, European Union legislation must, so far as possible, be interpreted in a manner that is consistent with international law, in particular where its provisions are intended specifically to give effect to an international agreement concluded by the European Union (see, inter alia, Case C-341/95 *Bettati* [1998] ECR I-4355, paragraph 20, and Case C-306/05 *SGAE* [2006] ECR I-11519, paragraph 35).”²² The consistent interpretation of

¹⁹ Case F-11/08, judgement from the Civil Service Tribunal of 4 June 2009, *Jörg Mölling v Europol*, §69.

²⁰ Opinion of advocate general Ms Juliane Kokott, delivered on 23 December 2015, Case C-547/14 *Philip Morris Brands SARL and others v Secretary of State for Health*, § 1.

²¹ Case C-547/14 *Philip Morris Brands SARL and others v Secretary of State for Health*

²² C-135/10, *Società Consortile Fonografici (SCF)*, 15 March 2012, §51 ; see also C-61/94 *Germany v Council*, 10 September 1996, §52; C-76/00 P, *Petrolub*, 9 January 2003, §56; C-286/02, *Bellio*, 1st April 2004, §33; C-511/13 P, *Philips Lighting Poland S.A.*, 8 March 2016, §60.

secondary legislation with international law is not conditioned by the direct applicability of the norm of international law,²³ but it nevertheless supposes that the Union be bound by this norm in the international legal order.

In this particular case, the Union might not yet be bound to implement the Seoul protocol; however, the directive was adopted in order to implement the World Health Organization framework convention.²⁴ In fact, the latter also contains provisions regarding track and trace. Particularly, article 15(2) of the framework convention reads that Parties shall adopt all “measures to ensure that *all* unit packets and packages of tobacco products and *any outside packaging* of such products are marked to assist Parties in determining the origin of tobacco products.” Of course, the framework convention does not bind the parties to adopt a track and trace system – which is the object of the protocol – but only to consider the adoption of such a system.²⁵ Nevertheless, as long as the framework convention is to apply to all packets and any outside packaging of tobacco products, it is all the more logical to consider that when a party adopts (on purpose) a track and trace system, it must ensure that such a system does not carry the risk that certain units of conditioning circumvent the system. However, this would be the case if the tobacco industry was entrusted with the responsibility to affix the unique identifier.

Henceforth, it is necessary to take account of the prohibition contained in the protocol. Surely, it has not entered into force in the international legal order. Still, it was often ruled according to standard case-law that an external agreement not yet entered into force, but whose instrument of ratification had been deposited by the Community (the Union), could serve as a ground for an action in annulment of an act of secondary legislation.²⁶ The reason for relying to that end on an external agreement not yet entered into force is the principle of good faith which “is the corollary in international public law of the principle of the protection of legitimate expectations, which forms part of the European Union legal order.”²⁷ It can be considered that if the external agreement not yet entered into force can be used as a ground in the contentious proceedings about the legality of secondary legislation, member states must also take it into account when they transpose such act in their domestic legal order. Indeed, the principle of sincere cooperation requires member states to “take any appropriate measure, general or particular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the Union.”²⁸ The adoption, today, of transposition measures that will be contrary tomorrow to an international obligation of the Union which is already known and to which the Union clearly expressed its intention to adhere to does not appear consistent

²³ C-53/96, *Hermès*, 16 June 1998, §28; C-300/98 and C-392/98, *Dior*, 14 December 2000, §47.

²⁴ Directive, recital 7 and article 1.

²⁵ Framework convention, article 15 (2) b).

²⁶ Endnote 13.

²⁷ T-468/08, *Tisza Erőmű v Commission*, 30 avril 2014, §321.

²⁸ Article 4(2) Treaty on the European Union. It must be reminded that international treaties concluded by the Union are considered in its legal order as acts adopted by its institutions: Case 181/73, *Haegeman*, 30 April 1974, §§4-5.

with the principle of sincere cooperation. It is even more so when the member state that transposes secondary legislation is bound by an obligation of good faith on the grounds of international law as codified by article 18 of the Vienna convention on the law of treaties, for the reason that it expressed its consent to be bound by the relevant external agreement, as France did as regards the protocol.

In sum, it can be affirmed that the directive is not opposed to member states being in charge of the whole track and trace system; furthermore, read as a whole in light of primary law and the international obligations of the Union and of its member states, it is safe to consider that, in addition to prohibiting data storage by the tobacco industry, the directive prevents member states from entrusting the management of other elements of the track and trace system to the tobacco industry. Amending the directive to remove any ambiguity would surely be useful, even though it is unnecessary to reach to above conclusion.

Of course, the preceding reasoning is valid for all delegated and implementing acts to be adopted on the grounds of the directive. And it is not superfluous to add that in the drafting of these acts, the Commission is liable on the grounds of an action for failure to act.

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