Reports of Cases

OPINION OF ADVOCATE GENERAL
SZPUNAR
delivered on 14 October 2021 [1]

Case C-452/20

PJ
v
Agenzia delle dogane e dei monopoli – Ufficio dei monopoli per la Toscana, Ministero dell'Economia e delle Finanze

(Request for a preliminary ruling from the Consiglio di Stato (Council of State, Italy))

(Reference for a preliminary ruling – Approximation of laws – Manufacture, presentation and sale of tobacco products and related products – Cooperation and enforcement – Rules on penalties – Effective, proportionate and dissuasive penalties – Obligation on sellers of tobacco products to ensure that tobacco purchasers have reached the age set by national law for the purchase of tobacco products – Suspension of trading licence for a period of 15 days)

I. Introduction

1. By its request for a preliminary ruling, the referring court asks the Court for clarification so that it can assess the compliance of the rules on penalties applicable to infringements of the prohibition on the sale of tobacco products to minors with EU law and, more specifically, with the principle of proportionality. A priori, this request seems to be perfectly in line with classic cases concerning the interpretation of EU law.

2. However, it should be noted that there is a particularity in the present case deriving from the source of the prohibition, infringements of which are penalised by the rules at issue in the case in the main proceedings.

3. Whilst the question referred to the Court for a preliminary ruling is asked from the perspective of Directive 2014/40/EU, [2] the obligation for Member States to adopt measures to prevent the sale of tobacco products to minors, at issue in the present case, is laid down not in that directive, but in an international agreement to which Member States and the European Union are parties.

[1] Original language: French.

[2] Directive of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1).

4. Consequently, the preliminary question raised by this request for a preliminary ruling is whether, and, as the case may be, on what basis, the principle of proportionality restricts the leeway enjoyed by Member States with regard to the system of penalties at issue in the main proceedings.

II. Legal framework

A. The FCTC

5. The World Health Organization (WHO) Framework Convention on Tobacco Control, signed in Geneva on 21 May 2003 ('the FCTC'), was approved on behalf of the European Union by Decision 2004/513/EC. [3]

6. Article 16(1) and (6) of the FCTC provides:

'1. Each Party shall adopt and implement effective legislative, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or [18]. These measures may include:

(a) requiring that all sellers of tobacco products place a clear and prominent indicator inside their point of sale about the prohibition of tobacco sales to minors and, in case of doubt, request that each tobacco purchaser provide appropriate evidence of having reached full legal age;

(b) banning the sale of tobacco products in any manner by which they are directly accessible, such as store shelves;

(c) prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors; and

(d) ensuring that tobacco vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors.

…

6. Each Party shall adopt and implement effective legislative, executive, administrative or other measures, including penalties against sellers and distributors, in order to ensure compliance with the obligations contained in paragraphs 1[to]5 of this Article.'

[3] Council Decision of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control (OJ 2004 L 213, p. 8).

B. Directive 2014/40

7. Recitals 7, 8, 21 and 60 of Directive 2014/40 state:

'(7) Legislative action at Union level is also necessary in order to implement the [FCTC], the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.

(8) In accordance with Article 114(3) [TFEU], a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people.

…

(21) In line with the purposes of this Directive, namely to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people, and in line with Council Recommendation 2003/54/EC[,[4]] Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures that lay down and enforce age limits.

…

(60) Since the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives'.

8. Article 1 of that directive provides:

'The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

[4] Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (OJ 2003 L 22, p. 31).

(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;

(c) the prohibition on the placing on the market of tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the obligation to submit a notification of novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;

in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the [FCTC].'

9. Article 23(3) of that directive provides:

'Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures that are necessary to ensure that these penalties are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial administrative penalty that may be imposed as a result of an intentional infringement may be such as to offset the economic advantage sought through the infringement.'

C. Italian law

10. Article 25 of the regio decreto n. 2316 – Testo unico delle leggi sulla protezione ed assistenza della maternità ed infanzia (Royal Decree No 2316 – Consolidated law on the protection and assistance of motherhood and childhood) [5] of 24 December 1934, as replaced by Article 24(3) of decreto legislativo n. 6 – Recepimento della direttiva 2014/40/UE sul ravvicinamento delle disposizioni legislative, regolamentari e amministrative degli Stati membri relative alla lavorazione, alla presentazione e alla vendita dei prodotti del tabacco e dei prodotti correlati e che abroga la direttiva 2001/37/CE (Legislative Decree No 6 transposing Directive 2014/40) [6] of 12 January 2016 ('the national provision at issue'), provides:

'Anyone who sells tobacco products or electronic cigarettes or refill containers containing nicotine or novel tobacco products shall require the purchaser to produce an identity document at the time of sale, unless it is obvious that the latter is of legal age.

Anyone who sells or supplies tobacco products or electronic cigarettes or refill containers containing nicotine or novel tobacco products to minors under the age of 18 shall be liable to a financial administrative fine of EUR 500 to EUR 3 000 and a 15-day trading licence suspension. For repeat offences, a financial administrative fine of EUR 1 000 to EUR 8 000 shall apply and the trading licence shall be revoked.'

[5] GURI No 47 of 25 February 1935, p. 811.

[6] GURI No 13 of 18 January 2016, p. 102.

III. The facts in the main proceedings, the procedure and the question referred for a preliminary ruling

11. The appellant in the main proceedings is the holder of a trading licence for a tobacconist's shop authorising him to sell tobacco products which are the subject of a State monopoly in Italy.

12. In February 2016, during an inspection, the Customs Agency discovered that the appellant in the main proceedings had sold cigarettes to a minor.

13. In application of the national provision at issue, the Customs Agency fined the appellant in the main proceedings EUR 1 000 and imposed an ancillary administrative penalty by suspending his trading licence for a tobacconist's shop for a period of 15 days.

14. The appellant in the main proceedings paid the fine imposed on him without dispute. By contrast, he contested the ancillary administrative penalty, by which his tobacconist's shop trading licence had been suspended, before the Tribunale amministrativo regionale per la Toscana (Regional Administrative Court, Tuscany, Italy).

15. The appellant in the main proceedings claimed, in particular, that the suspension of his trading licence was unreasonable and disproportionate because the penalty of suspension had been imposed on him following a single first-time offence.

16. The appellant in the main proceedings considered that the national provision at issue was incompatible with Directive 2014/40 and, for that reason, asked the Tribunale amministrativo regionale per la Toscana (Regional Administrative Court, Tuscany) to refer a question to the Court of Justice for a preliminary ruling.

17. By judgment of 27 November 2018, the Tribunale amministrativo regionale per la Toscana (Regional Administrative Court, Tuscany) dismissed the action of the appellant in the main proceedings, taking the view that, in the light of the interpretation of recital 8 and Article 23(3) of Directive 2014/40, it cannot not be considered that the national legislation at issue was incompatible with EU law.

18. The appellant in the main proceedings brought an appeal against that judgment before the Consiglio di Stato (Council of State, Italy). He argued again that the provision at issue in the main proceedings was incompatible with Directive 2014/40. In particular, he claimed that the provision at issue gave precedence to the precautionary principle in order to protect the right to health of minors, thus infringing the principle of proportionality.

19. According to the appellant in the main proceedings, the Italian legislature has introduced penalties that go beyond merely offsetting the economic advantage obtained from the sale of tobacco products to minors. Those penalties seek to ensure the highest level of protection of human health to the detriment of the economic interest of retailers. In doing so, the Italian legislature has distorted the necessary balance between the various fundamental rights protected by EU law.

20. In that regard, the referring court considers that it is clear from recitals 8 and 21 and the last paragraph of Article 1 of Directive 2014/40 that the protection of human health, especially that of young people, takes precedence over the right of economic operators to carry on a business.

21. The referring court takes the view that, when examining the proportionality of the penalties at issue in the main proceedings, account must be taken of the preponderance which Directive 2014/40 gives to protecting the health of young people. That preponderance makes it possible to put into effect and define the principle of proportionality.

22. It also considers that, in weighing up the interest of protecting the health of young people, on the one hand, and the right of economic operators to carry on the business of selling tobacco products, on the other, Article 23(3) of Directive 2014/40 empowers the Member States to lay down rules on penalties with the aim of prohibiting tobacco consumption by minors. That provision requires only that the penalties be effective, proportionate and dissuasive. In addition, whilst that provision provides that the financial penalties imposed may be such as to offset the economic advantage sought through the infringement, the fact remains that the EU legislature does not exclude non-financial administrative penalties. It should therefore be considered that Article 23(3) of Directive 2014/40 provides, by way of example, for the possibility of offsetting the economic advantage obtained from the sale of tobacco products through the imposition of financial penalties.

23. In that context, the referring court considers that, by providing for the suspension of trading licences authorising economic operators to sell tobacco products, the Italian legislature has, in accordance with Directive 2014/40, given precedence to the protection of human health over the right of economic operators to sell tobacco products. It points out that, in the light of the importance of the protection of the health of young people and the need for penalties to be dissuasive in order for the protection to be effective, the retailers' economic loss is reasonably justified, and the penalty at issue in the main proceedings is dissuasive and effective.

24. With regard to the period during which a trading licence may be suspended, the referring court states that, in some circumstances, under Italian law, the maximum period of suspension could extend to six months.

25. In those circumstances, the Consiglio di Stato (Council of State) decided, by decision of 5 August 2020, received at the Court on 23 September 2020, to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'Does the second paragraph of Article 25 of [Royal Decree No 2316 of 24 December 1934], as replaced by [the national provision at issue] – inasmuch as it provides that "anyone who sells or supplies tobacco products or electronic cigarettes or refill containers containing nicotine or novel tobacco products to minors under the age of 18 shall be liable to a financial administrative fine of EUR 500 to EUR 3 000 and a 15-day trading licence suspension" – infringe the EU principle of proportionality and the precautionary principle, as set out in Article 5 TEU, in Article 23(3) of Directive 2014/40, and in recitals 21 and 60 of that directive, by giving precedence to the precautionary principle without mitigating it with the principle of proportionality, and thus disproportionately sacrificing the interests of economic operators to the protection of the right to health, thereby failing to ensure that a proper balance is struck between the different fundamental rights and, what is more, doing so by means of a penalty that, contrary to recital 8 of [that directive], does not effectively pursue the objective of discouraging smoking prevalence among young people?'

26. Written observations were submitted by the appellant in the main proceedings, the Italian and Hungarian Governments, and the European Commission. No hearing was held.

IV. Analysis

27. By its single question, the referring court asks, in essence, whether the principle of proportionality set out in Article 5 TEU and given concrete expression in Article 23(3) of Directive 2014/40, and the precautionary principle, preclude a national provision which, in the event of a first-time infringement of the prohibition on the sale of tobacco products to minors, provides, in addition to the imposition of an administrative fine, for the 15-day suspension of the trading licence authorising the economic operator which infringed that prohibition to sell tobacco products.

28. In order to answer that question, it is first necessary to verify whether the two principles to which the referring court refers are applicable to the situation at issue in the main proceedings. It is apparent from the written observations submitted by the parties that the applicability of those principles to the situation at issue in the present case is not clear.

A. The applicability of the principle of proportionality and the precautionary principle

1. The principle of proportionality

29. In asking the Court for clarifications with regard to the principle of proportionality, the referring court states that that principle is set out in Article 5 TEU and Article 23(3) of Directive 2014/40.

30. Consequently, it is necessary to examine, in the first place, whether Article 5 TEU and Article 23(3) of Directive 2014/40, which gives concrete expression to the principle of proportionality, apply to a situation such as that at issue in the main proceedings. If not, it would be necessary, in the second place, to verify whether the national provision at issue implements EU law. Indeed, the principle of proportionality is a general principle of EU law that must be observed by national legislation which falls within the scope of EU law or implements that law;[7] moreover, the Charter of Fundamental Rights of the European Union ('the Charter'), which also refers to that principle, applies only in the context of the implementation of EU law.

(a) The applicability of Article 5 TEU

31. The principle of proportionality is provided for in Article 5(4) TEU. In accordance with the first subparagraph of that provision, under the principle of proportionality, the content and form of EU action is not to exceed what is necessary to achieve the objectives of the Treaties. The second subparagraph of that provision concerns the EU institutions and the requirement for them to comply with the principle of proportionality when they act in the exercise of a competence. Article 5(4) TEU thus relates to the action of the EU institutions.

[7] Judgment of 4 October 2018, *Link Logistik N&N* (C-384/17, EU:C:2018:810, paragraph 40).

32. In the present case, the appellant in the main proceedings challenges a provision of national law contained in a royal decree adopted by the Italian legislature, which lays down the penalties imposed by the Customs Agency. The situation at issue in the main proceedings does not therefore concern the activities of the EU institutions and, as a result, Article 5(4) TEU does not apply in the present case. [8]

33. It follows that it is not necessary to answer the question referred in so far as it concerns the interpretation of Article 5(4) TEU.

(b) The applicability of Article 23(3) of Directive 2014/40

(1) Summary of the problem

34. Article 23(3) of Directive 2014/40 provides that Member States are to lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to that directive.

35. However, Directive 2014/40 does not impose an obligation on Member States to adopt measures to prevent the sale of tobacco products to minors under the age of 18. That directive does not lay down any general obligation on sellers of tobacco products to ensure that purchasers have reached the age set by national law for the purchase of such products.

36. The absence of such an obligation in Directive 2014/40 is due to the extent of harmonisation achieved by that directive. As noted by the Court, it follows from the general scheme of Directive 2014/40 that the latter does not bring about full harmonisation in relation to, inter alia, the sale of tobacco products and related products. [9] Recital 48 of that directive states that it does not harmonise domestic sales arrangements or domestic advertising, nor does it introduce an age limit for electronic cigarettes or refill containers. That recital also states that Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so.

37. Although the obligation to adopt measures to prevent the sale of tobacco products to minors is not laid down in Directive 2014/40, such an obligation is nevertheless imposed on the Member States. That obligation is set out in the FCTC, a mixed agreement concluded, signed and ratified by all the Member States, and approved by the European Union. [10] Article 16(1) of the FCTC requires each party to that framework convention to adopt and implement measures to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or under 18 years of age.

38. In order for Article 23(3) of Directive 2014/40 to be applicable to the situation at issue in the main proceedings, it would be necessary to consider that, where a prohibition on the sale of tobacco products to minors, imposed by Article 16(1) of the FCTC, is adopted by an EU Member State, that prohibition results from a national provision adopted 'in application of [that] directive'.

[8] See, to that effect, judgment of 25 July 2018, *TTL* (C-553/16, EU:C:2018:604, paragraphs 33 and 35), and order of 13 February 2020, *MAK TURS* (C-376/19, not published, EU:C:2020:99, paragraphs 18 and 19).

[9] Judgment of 4 May 2016, *Philip Morris Brands and Others* (C-547/14, EU:C:2016:325, paragraph 77).

[10] See the first sentence of recital 7 of Directive 2014/40. With regard to the classification of the FCTC as a mixed agreement, see, also, Klamert, M. 'Public Health Policy', in Koffman, H.C.H., Rowe, G.C. and Türk, A.H. (ed.), *Specialized Administrative Law of the European Union: A Sectoral Review*, Oxford University Press, Oxford, 2012, p. 422.

(2) Position of the parties

39. The appellant in the main proceedings, the Italian Government and the Commission are of the view that Article 23(3) of Directive 2014/40 applies to the situation at issue in the main proceedings.

40. According to the appellant in the main proceedings, EU law merely requires Member States to introduce and enforce age limits with regard to tobacco consumption. In support of that claim, he relies, in particular, on Article 1 and recital 21 of Directive 2014/40.

41. By contrast, the Italian Government maintains, referring to recital 48 of Directive 2014/40, that that directive does not govern the sale of tobacco to minors. However, in the Italian Government's view, the extent of harmonisation achieved by that directive does not preclude a national provision which determines a penalty applicable from being examined in the light of Article 23(3) of that directive. The Italian Government relies on that provision, and on Article 5 TEU, in its proposed answer to the question referred.

42. As for the Commission, it states unambiguously that the absence of measures to harmonise the prohibition on the sale of tobacco products to minors in Directive 2014/40 does not prevent the verification of compliance with Article 23(3) of that directive, not only with regard to measures aimed at penalising the infringement of specific obligations laid down in that directive, but also with regard to all other measures adopted by the Member States with the aim of achieving the objectives pursued by that directive and implementing EU law. The Commission points out, in that regard, that Directive 2014/40 refers directly to the FCTC,[11] which requires, in Article 16 thereof, the adoption of effective measures to prohibit the sale of tobacco products to minors. There is therefore a functional link between Article 23(3) of Directive 2014/40 – which defines the principles that must be respected by the penalties adopted by the Member States to achieve the objectives pursued by that directive – and the penalties provided for by the national legislation at issue in the event of non-compliance with the prohibition on the sale of tobacco products to minors.

(3) Assessment

43. It is true that the national provision at issue, which determines the penalty applicable to infringements of another national provision prohibiting the sale of tobacco products to minors, appears in an Italian legislative text the title of which indicates that it concerns the transposition of Directive 2014/40. It should also be noted, in that regard, that Article 29(2) of that directive requires that, when Member States adopt transposition measures, they are to contain a reference to that directive. A priori, that may lead one to think that the prohibition on the sale of tobacco products to minors results from a national provision adopted in application of Directive 2014/40, with the result that Article 23(3) of that directive should also apply in relation to that penalty.

[11] See recital 7 of Directive 2014/40.

44. Nevertheless, it should be noted, in the first place, that Article 29 of Directive 2014/40 makes a distinction between national provisions brought into force by a Member State to comply with that directive [12] and those adopted in the field covered by that directive. [13] The harmonisation achieved by Directive 2014/40 does not cover all aspects relating to the field covered by that directive.

45. In that context, in the second place, the harmonisation achieved by Directive 2014/40 does not include the obligation to adopt measures to prevent the sale of tobacco products to minors.

46. Indeed, recital 20 of Recommendation 2003/54 states that it is important to ensure that the measures contained in that recommendation are consistent with the draft elements of the FCTC. In line with that guidance, Article 1 of Recommendation 2003/54 recommended the adoption by the Member States of measures to prevent tobacco sales to children and adolescents.

47. Next, recital 7 of Directive 2014/40 suggests that it is the result of legislative action by which the FCTC was implemented at EU level.

48. In addition, recital 21 of Directive 2014/40 raises Recommendation 2003/54 to the same level as the objective of that directive, that is to say, the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people. Moreover, it states that Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures that lay down and enforce age limits.

49. In the same vein, recital 48 of Directive 2014/40 confirms that it does not harmonise domestic sales arrangements or domestic advertising, nor does it introduce an age limit for electronic cigarettes or refill containers. That recital also states that Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so. In doing so, it in no way states that the leeway enjoyed by Member States is limited by Directive 2014/40.

50. Lastly, in that regard, Article 1 of Directive 2014/40 clarifies that the objective of that directive is to approximate the provisions of the Member States in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the European Union under the FCTC.

51. However, the encouragement given to Member States, in recitals 21 and 48 of Directive 2014/40, does not give rise, in that directive, to a provision imposing an obligation, such as the one set out in Article 16(1) of the FCTC. [14] The general obligation to adopt measures to prevent the sale of tobacco products to minors is therefore not present. From reading the matters covered by the harmonisation achieved by Directive 2014/40, it is common ground that the only subject matter similar to that referred to in Article 16(1) of the FCTC is that referred to in Article 1(d) and Article 18 of that directive, and concerns the cross-border distance sales of tobacco products. In accordance with Article 18(4) of that directive, retail outlets engaged in cross-border distance sales are to operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination.

[12] See Article 29(1) and (2) of Directive 2014/40.

[13] See Article 29(3) of Directive 2014/40, which provides that Member States are to communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this directive.

[14] See point 35 of this Opinion.

52. Furthermore, although Article 18 of Directive 2014/40 governs a subject matter similar to that referred to in Article 16 of the FCTC, its *ratio legis* seems to be quite different. To some extent, that difference may explain the extent of harmonisation achieved by the EU legislature through that directive, which does not concern the subject matter targeted by the FCTC. So far as concerns cross-border distance sales of tobacco products, referred to in Article 18 of Directive 2014/40, the Commission maintained, during the *travaux préparatoires*, that it was almost impossible for a Member State to regulate tobacco internet sales, in particular regarding the minimum legal age to purchase tobacco, if such sales are unregulated in other Member States.[15] By contrast, in legal literature, the measures provided for in Article 16 of the FCTC are essentially national measures and do not clearly justify the existence of an international treaty.[16] It could be argued that, a fortiori, those measures do not justify the intervention of the EU legislature either.

53. In the third place, although Directive 2014/40 does not contain a provision reproducing the content of Article 16(1) of the FCTC, that framework convention does, however, contain a provision similar to that of Article 23(3) of Directive 2014/40, namely Article 16(6) thereof. That provision is more concise than that of Directive 2014/40. It follows from that provision that the penalties provided to ensure compliance with the obligation to prevent the sale of tobacco products to children and adolescents must be 'effective'.

54. The Member States joined the FCTC well before the date of transposition of Directive 2014/40. Before that date, the penalties applicable to infringements of a national provision governing the prohibition on the sale of tobacco products to minors had to be determined in accordance with Article 16(6) of that framework convention. This is still the case after the transposition of Directive 2014/40.

55. In the fourth place, in so far as the provisions of the FCTC are binding on the Member States and the European Union, that framework convention thus constitutes a mixed agreement and the provisions form an integral part of EU law. It is clear that, in the present case, the provisions in question concern aspects that have an influence on the functioning of the internal market and are therefore matters in which the European Union has competence. Complying with the provisions of the FCTC and introducing measures to prevent the sale of tobacco products to minors under the age of 18 thus results from an international obligation embedded in the EU legal order. The implementation of the FCTC therefore amounts to the implementation of EU law, without necessarily requiring the adoption of provisions aimed at implementing Directive 2014/40.

56. That consideration is not called into question by the Commission's argument that Article 23(3) of Directive 2014/40 applies to the situation at issue in the main proceedings, on the ground that there is a functional link between that provision and the penalties provided for by the national provision at issue.

[15] Proposal for a Directive of the European Parliament and of the Council 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 (COM(2012) 788 final).

[16] Burci, G.L., *La convention-cadre de l'O.M.S. pour la lutte antitabac*, United Nations Audiovisual Library of International Law, legal.un.org/avl/, p. 4. The author points to two reasons that may explain the appeal of an international treaty, namely the fact that establishing measures as international obligations made it possible, first, to protect States from any pressure from the tobacco industry and, second, to strengthen the power of health ministers by allowing them to invoke those obligations.

57. The Commission's argument appears to be based, in essence, on alleged parallelism between the objectives pursued by Directive 2014/40 and those covered by the national provision at issue, on the basis of the judgment in *Siragusa*,[17] to which the Commission refers. According to that judgment, in order to determine whether national legislation involves the implementation of EU law for the purposes of Article 51 of the Charter, some of the points to be determined are whether that legislation is intended to implement a provision of EU law, the nature of that legislation and whether it pursues objectives other than those covered by EU law. However, in view of those elements, it should be observed that the national provision at issue is instead intended to implement Article 16 of the FCTC which, as a provision of an agreement entered into by the European Union, is an integral part of its legal order.

(c) The applicability of the principle of proportionality as a general principle of EU law

58. Although Article 23(3) of Directive 2014/40 is not applicable to the situation at issue in the main proceedings, the principle of proportionality applies to that situation as a general principle of EU law.

59. On the one hand, the principle of proportionality, which requires the Member States to adopt measures that are appropriate for attaining the objectives pursued and do not go beyond what is necessary for attaining them, must be observed by national legislation which falls within the scope of EU law or implements that law.[18] International agreements concluded by the European Union, the provisions of which form an integral part of its legal order, are not in principle 'impenetrable' to primary law, including general principles of EU law.[19] Consequently, consistent with that idea and in so far as the FCTC forms an integral part of EU law, its implementation must observe the principle of proportionality.

60. On the other hand, in accordance with Article 52(1) of the Charter, subject to the principle of proportionality, limitations on the exercise of the rights and freedoms recognised by the Charter may be made only if they are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others. As regards their proportionality, the same is true, in essence, for limitations on the exercise of the rights recognised by the Charter for which provision is made in the Treaties (Article 52(2) of the Charter).[20] In any event, the fact that a limitation on the exercise of such rights and freedoms derives from an international obligation forming an integral part of EU law cannot imply that the limitation need not observe the principle of proportionality.

2. The precautionary principle

61. The Commission considers that the precautionary principle is not applicable in the present case, in so far as there is no uncertainty with regard to the risks to human health associated with the sale of tobacco products to minors.

[17] Judgment of 6 March 2014 (C-206/13, EU:C:2014:126, paragraph 25).

[18] Judgment of 4 October 2018, *Link Logistik N&N* (C-384/17, EU:C:2018:810, paragraph 40).

[19] Lenaerts, K. and De Smijter, E., 'The European Union as an Actor under International Law', *Yearbook of European Law*, 2000, Vol. 19, p. 105.

[20] The principle of proportionality has various sources in EU law and finds various expressions as a general principle of EU law. That principle guarantees, in particular, the unfettered exercise of the fundamental freedoms of the internal market and is referred to in Article 49(3) and Article 52(1) of the Charter. In the present case, it is not necessary to distinguish between those sources or expressions.

62. I agree with the Commission in that regard.

63. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, the precautionary principle justifies the adoption of restrictive measures.[21] That principle does not come into play in a situation where there is no element of uncertainty as to the existence or extent of a risk.[22]

64. As indicated in the preamble to the FCTC, the parties to that framework convention recognised that scientific evidence had unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability. In this sense, although the encouragement given in recitals 21 and 48 of Directive 2014/40 does not result in a provision reproducing the content of Article 16(1) of the FCTC, that encouragement indicates that the EU legislature has recognised the relevance of scientific evidence. There is nothing to suggest that the studies which led to the adoption of the FCTC and Directive 2014/40 have characteristics such as to justify applying the precautionary principle.

65. Consequently, there is no need to answer that aspect of the question referred in so far as it concerns the interpretation of the precautionary principle and to the extent that the precautionary principle does not apply to the situation at issue in the main proceedings. It is therefore necessary to provide the referring court with information allowing it to assess whether the national provision at issue observes the principle of proportionality as a general principle of EU law only.

B. Substance

66. The appellant in the main proceedings claims, first of all, that, by the national provision at issue, the Italian legislature distorted the necessary balance between the various fundamental rights protected by EU law.

67. Next, he argues that the national provision at issue does not effectively pursue the objective of discouraging smoking prevalence among young people, given that it adversely affects the economic activity of the offender rather than actively reducing smoking prevalence among young people.

68. Lastly, in his view the penalty system provided by the national provision at issue does not comply with the principle of proportionality because of the excessive severity of the penalties laid down. The objective to reduce smoking prevalence among young people could have been pursued with less onerous and less restrictive penalties, by means of a progressive, tiered penalty system, capable of ensuring that an offender would receive a penalty that would not have the effect of jeopardising his or her 'survival' as an economic operator from the first offence. Furthermore, retailers are not always able to verify with certainty the buyer's age.

69. Having regard to the claims made by the appellant in the main proceedings, which thus underlie the question referred, and in the light of the fact that Article 23(3) of Directive 2014/40 does not apply to the situation at issue in the main proceedings, those claims should be understood in the sense that the national provision at issue must be regarded as a limitation on

[21] See, in particular, judgment of 29 April 2010, *Solgar Vitamin's France and Others* (C-446/08, EU:C:2010:233, paragraph 70).

[22] See, to that effect, my Opinion in *Deutsche Parkinson Vereinigung* (C-148/15, EU:C:2016:394, point 69).

the exercise of the freedom to conduct a business and, possibly, the right to property, by which the Italian legislature seeks to attain the legitimate aim pursued by the prohibition on the sale of tobacco products to minors, that is to say, the protection of human health in order to reduce, inter alia, smoking prevalence among young people. In that regard, the referring court considers that the claims made by the appellant in the main proceedings relating to the non-compliance of the national provision at issue are unfounded. However, there is no judicial remedy under national law against its decisions and the referring court was therefore required to make a reference for a preliminary ruling concerning the interpretation of EU law.

70. In those circumstances, it should be borne in mind that, in the absence of harmonisation at EU level in the field of penalties applicable, the Member States remain free to choose the penalties which seem appropriate.

71. However, rules on penalties applicable to infringements of the prohibition on the sale of tobacco products to minors, such as those at issue in the main proceedings, must, as is apparent from the considerations set out in points 53 and 58 of this Opinion, observe the requirement for effectiveness provided for in Article 16(6) of the FCTC, and the principle of proportionality. [23]

72. Moreover, whilst it is for the referring court – which alone has jurisdiction to interpret and apply national law – to assess whether, in the present case, the suspension of a trading licence for a tobacconist's shop, in addition to the fine imposed, is proportionate to attaining the legitimate aim pursued by the prohibition on the sale of tobacco products to minors, that is to say, the protection of human health in order to reduce, inter alia, smoking prevalence among young people, the fact remains that the Court can provide it with guidance as to the interpretation of EU law allowing it to determine whether this is the case.

73. Against that background, in the first place, as regards the limitations resulting from the system of penalties applicable to infringements of the prohibition on the sale of tobacco products to minors, such as that at issue in the main proceedings, the freedom to conduct a business and the right to property provided for, respectively, in Articles 16 and 17 of the Charter, are at stake.

74. The freedom to conduct business and the right to property are not absolute. Any limitation on their exercise may be made, subject to the principle of proportionality, only if it is necessary and genuinely meets objectives of general interest recognised by the European Union. The protection of health and the reduction of smoking prevalence among young people are undeniably objectives of general interest.

75. In that context, in the judgment in *Swedish Match*, [24] the Court examined the impact of the prohibition on the marketing of tobacco products for oral use which are particularly attractive to young people, laid down in Article 8 of Directive 2001/37/EC, [25] which preceded Directive 2014/40. According to the Court, the obstacle to the freedom to pursue an economic activity constituted by a prohibition measure cannot be regarded, in relation to the aim of protecting health, as a disproportionate interference with the right to exercise that freedom or with the

[23] By contrast, Article 23(3) of Directive 2014/40 does not apply to the situation at issue in the main proceedings. The fact that that provision provides that any financial administrative penalty such as to offset the economic advantage sought through the infringement may be imposed as a result of an intentional infringement has no direct impact on the outcome of the assessment of the compliance of the national provision at issue with EU law.

[24] Judgment of 14 December 2004 (C-210/03, EU:C:2004:802, paragraph 74).

[25] Directive of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products – Commission statement (OJ 2001 L 194, p. 26).

right to property. In a judgment constituting the continuation of that judicial 'saga',[26] the Court considered, with regard to a similar prohibition laid down in Directive 2014/40, that the objective of protection of health takes precedence over economic considerations, the importance of that objective being such as to justify even substantial negative economic consequences. A fortiori, the temporary suspension of a trading licence for a tobacconist's shop should not be regarded as a disproportionate infringement of the right to exercise the freedom to conduct business or the right to property.

76. In the second place, as to whether the suspension of a trading licence for a tobacconist's shop can effectively achieve the objective of reducing smoking prevalence among young people, it should be observed that, as the Italian Government argues, a financial penalty imposed in isolation is not an effective measure: knowing that they can purchase tobacco in a particular establishment, minors would go there, thus leading to a considerable increase in the profits of the owner of the establishment, and the Member State would have to use disproportionate resources in order to carry out daily checks.

77. In the third place, with regard to the claims made by the appellant in the main proceedings by which he criticises the national provision at issue on the ground that it is not a tiered or progressive system, it is true that the principle of proportionality requires that the penalty imposed corresponds to the seriousness of the offence.[27]

78. However, the requirement that the penalty imposed corresponds to the seriousness of the offence cannot necessarily lead to the prohibition of a system of penalties that, in the event of a first-time infringement, is neither tiered, nor progressive. Each infringement of the prohibition on the sale of tobacco products to minors, taken in isolation, generally has similar characteristics, both in terms of the number of products sold and the people to whom those products are made available. Accordingly, the application of a uniform and standardised penalty in terms of the suspension of the trading licence for a tobacconist's shop, in the event of a first-time infringement of that prohibition, does not appear to be contrary to the principle of proportionality.

79. Furthermore, in accordance with the national provision at issue, unlike the amount of the fine, which may vary from EUR 500 to EUR 3000, the suspension of the trading licence allowing the economic operator in question to sell tobacco products is always, in the event of a first-time infringement, for a fixed period of 15 days. Therefore, in the context of the national provision at issue, the correspondence between the penalty imposed and the seriousness of the offence is, at least to a certain extent, provided by the fine that accompanies the suspension of the trading licence for a tobacconist's shop.

80. In view of the foregoing considerations, it must be considered that the principle of proportionality must be interpreted as not precluding, in the event of a first-time infringement of the prohibition on the sale of tobacco products to minors, in addition to the imposition of an administrative fine, a 15-day suspension of the trading licence authorising the economic operator that infringed that prohibition to sell tobacco products.

[26] Judgment of 22 November 2018, *Swedish Match* (C-151/17, EU:C:2018:938, paragraph 54).

[27] Judgment of 4 October 2018, *Link Logistik N&N* (C-384/17, EU:C:2018:810, paragraph 45).

V. Conclusion

81. In the light of the foregoing considerations, I propose that the Court answer the question referred by the Consiglio di Stato (Council of State, Italy) as follows:

The principle of proportionality must be interpreted as not precluding, in the event of a first-time infringement of the prohibition on the sale of tobacco products to minors, in addition to the imposition of an administrative fine, a 15-day suspension of the trading licence authorising the economic operator that infringed that prohibition to sell tobacco products.