



Vastuvõtmise kuupäev : 31/07/2024

Case C-449/24

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

26 June 2024

Referring court:

Raad van State (Belgium)

Date of the decision to refer:

11 June 2024

Applicant:

DSE International BV

Defendant:

Belgische Staat

Subject of the action in the main proceedings

Application for annulment of the Koninklijk besluit van 28 oktober 2016 betreffende het fabriceren en het in de handel brengen van elektronische sigaretten (Royal Decree of 7 November 2022 amending the Royal Decree of 28 October 2016 on the manufacture and placing on the market of electronic cigarettes; ‘the contested Decree’), which seeks to partially transpose Directive 2014/40 as regards the regulation of electronic cigarettes

Subject and legal basis of the request for a preliminary ruling

By this request under Article 267 TFEU, the referring court seeks to ascertain whether the prohibition of additives that facilitate inhalation or nicotine uptake also applies to electronic cigarettes

Questions referred for a preliminary ruling

Is Article 20(3)(c) of Directive (EU) 2014/40, read in conjunction with Article 7(6) of the same Directive, to be interpreted as requiring Member States to prohibit, with regard to the placing on the market of electronic cigarettes and refill containers, nicotine-containing liquid from containing additives that facilitate inhalation or nicotine uptake, as provided for in Article 7(6)(d), even if the electronic cigarette does not produce combustion or smoke?

Provisions of EU law relied on

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, Article 1, Article 2(4), (5) and (9) and (16), Article 7(6), Article 20(3)(c), and Article 24(1);

Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, Article 7(1)(a).

Provisions of national law relied on

Koninklijk besluit van 28 oktober 2016 betreffende het fabriceren en het in de handel brengen van elektronische sigaretten, artikel 4; (Royal Decree of 28 October 2016 on the manufacture and placing on the market of electronic cigarettes), Article 4;

Koninklijk besluit van 7 november 2022 tot wijziging van het koninklijk besluit van 28 oktober 2016 betreffende het faciliteren en het in handel brengen van elektronische sigaretten, artikel 3 (Royal Decree of 7 November 2022 amending the Royal Decree of 28 October 2016 on the manufacture and placing on the market of electronic cigarettes), Article 3.

Succinct presentation of the facts and procedure in the main proceedings

- 1 The Royal Decree of 28 October 2016 on the manufacture and placing on the market of electronic cigarettes provides for the partial transposition of Directive 2014/40 as regards the regulation of electronic cigarettes.
- 2 On 28 June 202[2], the Hoge Gezondheidsraad (Superior Health Council; ‘HGR’) published Advisory Report No 9549, ‘Electronic cigarette: evolution’, which outlines the relative risks of e-cigarettes compared to smoking and not smoking. The report states that the e-cigarette is not without risk and is potentially harmful, but is estimated to be substantially less harmful than smoking and could even help

smokers to quit. The HGR therefore advocates making the restriction of smoking as well as vaping and other nicotine use an important part of policy, while policymakers should ensure that restricting vaping and other nicotine use does not undermine the objective of reducing the prevalence of smoking.

- 3 On 6 July 2021, pursuant to this report, the Belgian State notified the European Commission of a draft Royal Decree amending the aforementioned Royal Decree of 28 October 2016, in accordance with Directive 2015/1535, which regulates the procedure to be followed by Member States when adopting a technical regulation.
- 4 Article 3 of the draft Royal Decree that was thus notified seeks to amend Article 4 of the Royal Decree of 28 October 2016. The (draft) Article 4, §5 identifies four groups of prohibited additives.
- 5 On 7 July 2022, with reference to Articles 20(3)(c) and 7(6)(d) of Directive 2014/40, the federale overheidsdienst Volksgezondheid (Federal Public Health Service) asked the European Commission's Directorate-General for Health and Food Safety whether it may be inferred from these provisions: (i) that the prohibition of additives that facilitate nicotine inhalation also applies to electronic cigarettes containing nicotine, or whether Article 7(6) applies only to tobacco products and, (ii) if so, whether any Member States actually apply this prohibition to e-cigarettes.
- 6 On 22 July 2022, the European Commission replied that, by means of cross-referencing, Article 20(3)(c) makes Article 7(6) applicable to electronic cigarettes and refill containers by laying down the requirements for nicotine-containing liquid.
- 7 The Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and placing on the market of electronic cigarettes was issued on 7 November 2022.
- 8 However, the final text of Article 4 of the Royal Decree of 28 October 2016 as amended by Article 3 of the contested Royal Decree differs from the text of the draft. To the four groups of prohibited additives in Article 4, §4 of the Royal Decree of 28 October 2016, a fifth category was added, which was not included in the draft notified to the Commission, namely, additives that facilitate inhalation or nicotine uptake.
- 9 According to the report to the King, the addition of this new category aims to correct a transposition error.

The essential arguments of the parties in the main proceedings

- 10 The applicant raises two pleas, only the second of which is relevant in the context of the preliminary ruling procedure.

- 11 According to that second plea, Article 3 of the contested Decree exceeds the scope of the regulations concerning e-cigarettes and is contrary to Directive 2014/40, and in particular, Article 20(3)(c), read in conjunction with Article 7(6) of that Directive, in that it imposes stricter requirements on e-cigarettes than those provisions require. Moreover, Article 3 of the contested Decree, in so far as it prohibits ‘additives that facilitate inhalation or nicotine uptake’, is contrary to Article 24(1) of Directive 2014/40 because it imposes additional restrictions on additives in e-cigarettes compared with those set out in Directive 2014/40, whereas that provision does not allow Member States to lay down stricter requirements in national law.
- 12 The applicant points out that Article 20 of Directive 2014/40 regulates e-cigarettes, including the ingredients that e-cigarettes can contain. As regards e-cigarettes, Article 20(3)(c) requires Member States to ensure that the nicotine-containing liquid does not contain any of the additives listed in Article 7(6). Article 7(6) of the Directive contains ‘a list of four groups of additives to be prohibited for tobacco products in general’, and which - read in conjunction with Article 20(3)(c) - also apply to e-cigarettes. However, the (fifth) prohibition in Article 7(6)(d) of Directive 2014/40, on ‘additives that facilitate inhalation or nicotine uptake’, relates only to ‘tobacco products for smoking’. E-cigarettes, according to the applicant, cannot be considered ‘tobacco products for smoking’ as they do not contain tobacco and, consequently, there is no combustion (and therefore no smoke).
- 13 Indeed, Article 2(4) of Directive 2014/40 defines tobacco products as ‘products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not’. Article 2(9) defines ‘tobacco products for smoking’ as ‘tobacco products other than a smokeless tobacco product’ while the ‘electronic cigarette’ is defined as ‘a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges’ (Article 2(16)). It is thus clear from the wording of Article 7(6)(d) of Directive 2014/40 that the scope of the prohibition of additives that facilitate inhalation or nicotine uptake is specifically limited to ‘tobacco products for smoking’.
- 14 According to the applicant, if the legislature had wished to extend the scope of Article 7(6)(d) of Directive 2014/40 to e-cigarettes, this would have been made clear in the text of the relevant provisions. Transposing Article 7(6)(d) to e-cigarettes, a product category not (intended) for smoking, is therefore contrary to Directive 2014/40.
- 15 According to the applicant, Article 24(1) of the same Directive was also infringed. Under that provision, Member States may not in principle prohibit or restrict the placing on the market of tobacco or related products which comply with that Directive. Thus, they may not prohibit or restrict tobacco or related products

harmonised under Directive 2014/40, the free movement of which is guaranteed under Article 24(1).

- 16 The applicant argues that, according to settled case-law, the adoption of national rules that go beyond harmonisation constitutes an obstacle to the free movement of tobacco products or, as the case may be, related products (such as e-cigarettes) on the internal market, prohibited by Directive 2014/40. According to them, by adopting technical standards that do not exist in the other Member States, the defendant ‘is acting contrary to the smooth functioning of the internal market for tobacco-related products, such as electronic cigarettes’, one of the main objectives of Directive 2014/40. The ingredients that e-cigarettes may contain are subject to maximum standards and therefore full harmonisation.
- 17 Finally, the applicant refers to a similar case from 2016, when Germany sought to adopt new legislation to transpose Articles 7(6)(d) and 20(3)(c) of Directive 2014/40. On 20 May 2016, Germany submitted a notification of draft legislation to the Commission that included a prohibition on adding ‘additives that promote inhalation or nicotine uptake’ to ‘tobacco products for smoking, electronic cigarettes and refill containers’. Ultimately, the final text no longer referred to the prohibition of additives that facilitate inhalation or nicotine uptake in relation to e-cigarettes, while the prohibition was retained for tobacco products.
- 18 Until the conclusion of the review of Directive 2014/40 initiated by the European legislature, which may impose further restrictions on the additives authorised for e-cigarettes, Member States cannot adopt stricter national rules.
- 19 The applicant further points out that the prohibition of additives that facilitate inhalation or nicotine uptake was not included in the European Commission’s original proposal. On the advice of the Committee of the Regions, the proposal was subsequently amended to include the prohibition of ‘additives that enhance the addictive effects of nicotine’, but only in relation to tobacco products. The cross-reference in Article 20(3)(c) of Directive 2014/40 to Article 7(6) of that Directive on the composition of nicotine-containing liquids to the prohibited additives for tobacco products was only inserted at the European Parliament’s first reading. In the last, and also final, version of the Directive, it was finally clarified that the prohibition in (d) applies only to ‘tobacco products for smoking’.
- 20 That the European legislator therefore clearly did not intend e-cigarettes to be covered by the prohibition in Article 7(6)(d) of the Directive is, in their view, also not contradicted by the European Commission’s reply of 22 July 2022 to which the defendant refers. In it, the European Commission simply refers to the cross-reference that Article 20(3)(c) makes to Article 7(6), but does not confirm that this makes the prohibition of additives that facilitate inhalation or nicotine uptake [Article 7(6)(d)] applicable to e-cigarettes. The Subgroup on Electronic Cigarettes within the European Commission also did not take a position on this issue at its meetings. Moreover, according to the applicant, the fact that the defendant asked for clarification before issuing the contested Decree, indicates conclusively that

the defendant itself had doubts about the applicability of the prohibition to e-cigarettes.

- 21 In addition, the fact, too, that a limited number of other Member States have enacted similar barriers to trade, as the defendant argues, obviously does not justify the Belgian State's infringement of Directive 2014/40. Moreover, the various national laws on e-cigarettes, to which the defendant refers in its Response, make the same cross-reference contained in Directive 2014/40 to the prohibited additives in tobacco products. As such, this national legislation therefore only states that the prohibition of additives that facilitate inhalation or nicotine uptake applies to 'tobacco products for smoking' (and thus not to e-cigarettes). According to the applicant, this is the case in Finland, the United Kingdom and the Netherlands, among others. Consequently, contrary to the defendant's contention, these Member States do not have the same prohibition in place as Belgium, and that legislation cannot be used as evidence to apply the prohibition to e-cigarettes.
- 22 According to the defendant, the applicant's arguments are based on a misreading of Article 20(3) of Directive 2014/40. In fact, as regards e-cigarettes, that provision requires Member States to ensure that the nicotine-containing liquid does not contain any of the additives listed in Article 7(6). According to the defendant, Article 20(3)(c) therefore merely refers to the additives listed in Article 7(6) without distinguishing between the products in which those additives are used. This view, according to the defendant, is confirmed in the aforementioned European Commission email of 22 July 2022.

Succinct presentation of the reasoning in the request for a preliminary ruling

- 23 The parties disagree on the interpretation of Article 20(3), in conjunction with Article 7(6) of Directive 2014/40, of which the contested Royal Decree constitutes a partial transposition.
- 24 According to the preamble of the contested Royal Decree, the legal basis for the regulation of electronic cigarettes is to be found in Article 6, §1, (a) of the Wet van 24 januari 1977 'betreffende de bescherming van de gezondheid van de gebruikers op het stuk van de voedingsmiddelen en andere producten' (Law of 24 January 1977 'on the protection of the health of consumers with regard to foodstuffs and other products'). According to that provision, the King may, in the interest of public health or with the aim of preventing fraud or counterfeiting in this field, apply the measures referred to in Article 2, paragraphs 1 and 2, and in Article 3, 2°, (a), and 3°, (c), of that Law to, among other things, tobacco, tobacco-based products and similar products. Those measures include laying down rules and prescribing prohibitory measures relating to the manufacture and export of, and trade in, those products, including the possibility of determining the composition of tobacco (and similar) products.

- 25 Article 4, §4, 5°, of the Royal Decree of 28 October 2016, as amended by Article 3 of the contested Royal Decree, stipulates, with regard to electronic cigarettes, that the nicotine-containing liquid may not contain additives that facilitate inhalation or nicotine uptake. According to the report to the King, the addition of this new category aims to correct a transposition error.

- 26 The objective of Directive 2014/40, according to Article 1(f), is to approximate the laws, regulations and administrative provisions of the Member States concerning, in particular, 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 WHO Framework Convention for Tobacco Control (FCTC).

- 27 In this regard, the Directive distinguishes between, on the one hand, the rules applicable to ‘Tobacco products’ (Title II of the Directive) and, on the other hand, the rules applicable to ‘Electronic cigarettes and herbal products for smoking’ (Title III of the Directive).

- 28 Article 2 of the Directive defines the term ‘tobacco products’ as ‘products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not’ (Article 2(4)). A ‘smokeless tobacco product’ is ‘a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use’ (Article 2(5)). ‘Tobacco products for smoking’ are then ‘tobacco products other than a smokeless tobacco product’ (Article 2(9)). Finally, the term ‘electronic cigarette’ refers to ‘a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes may be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges’ (Article 2(16)).

- 29 According to Article 7(6)(d) of this Directive, which is part of Title II, ‘Tobacco products’, Chapter 1, ‘Ingredients and emissions’, Member States must prohibit the placing on the market of tobacco products for smoking containing additives that facilitate inhalation or nicotine uptake.

- 30 E-cigarettes (and refill containers) are covered by Article 20 of Directive 2014/40, which is part of Title III, ‘Electronic cigarettes and herbal products for smoking’. Article 20(3)(c) of Directive 2014/40 requires Member States to ensure that the nicotine-containing liquid does not contain additives listed in Article 7(6).

- 31 Finally, as regards freedom of movement, under Article 24(1) of this Directive, Member States may not prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

- 32 According to the referring court, it is not automatically self-evident that the cross-reference in Article 20(3)(c) of Directive 2014/40 - which relates to electronic cigarettes - to Article 7(6) - which relates to tobacco products - immediately also implies that the prohibition referred to in Article 7(6)(d) applies to electronic cigarettes (and refill containers) even though they do not cause combustion or smoke - which the defendant does not dispute. Indeed, the prohibition referred to in Article 7(6)(d) is expressly limited in that provision to ‘tobacco products for smoking’, namely, tobacco products other than smokeless tobacco products where the latter are tobacco products not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use. An electronic cigarette does not contain tobacco and does not produce combustion so that no smoke is developed from which, as the applicant submits, it could be inferred that the prohibition under Article 7(6)(d) cannot apply either to the electronic cigarette which does not produce smoke and is therefore a smokeless product. According to the referring court, the applicant therefore argues, not without foundation, that, if the European legislature had intended the prohibition laid down in Article 7(6)(d) also to apply to electronic cigarettes, it would have expressly provided for it in order to ensure legal certainty and uniform application of that prohibitory measure. According to the referring court, there is no incontrovertible evidence that this occurred.
- 33 The referring court observes that, although the Commission, in its answer of 22 July 2022 to the defendant’s question, does refer to the analogous application to electronic cigarettes of the prohibitions on additives laid down in Article 7(6) in general, it does not address the specific prohibitory measure laid down in point (d) of that provision and the effects of the restrictive phrase ‘tobacco products for smoking’ when applied to electronic cigarettes.
- 34 However, according to the referring court, that does not alter the fact that - in the light of the Directive’s objective of ensuring a high level of protection of human health, especially for young people - it is also reasonable to assume that, based on a textual reading of the cross-reference in Article 20(3)(c) to Article 7(6), in general, that provision also *prima facie* encompasses the prohibition of the placing on the market of electronic cigarettes containing additives which facilitate inhalation or nicotine uptake. Furthermore, this interpretation seems to find support in the fact that the distinction between ‘tobacco products for smoking’ and ‘smokeless tobacco products’, is not pertinent as far as the electronic cigarette is concerned, as the wording in Article 7(6)(d) refers to additives that ‘facilitate inhalation or nicotine uptake’. Consuming an electronic cigarette may not involve smoke, but the challenged prohibition does seem to seek, in general terms, to prevent the addition of additives that facilitate inhalation (with or without smoke) or nicotine uptake. While the electronic cigarette containing nicotine does not produce smoke, it does produce ‘vapours’ which can be inhaled so that it can be assumed that, with regard to that procedure too, the European legislature intended to prevent the addition of additives that facilitate inhalation or nicotine uptake.

- 35 The referring court finds, however, that it is unable, at this stage of the proceedings, to decide that question with the requisite degree of certainty and that it is therefore necessary to request a preliminary ruling from the Court of Justice of the European Union.