Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

18 December 2025*

(Appeal – Public health – Heated tobacco products – Withdrawal of certain exemptions – Delegated Directive (EU) 2022/2100 – Action for annulment – Standing – Fourth paragraph of Article 263 TFEU – Condition that the applicant must be individually concerned by the contested act – Limited class of economic operators – Reporting and notification obligations – Marketing authorisation)

In Case C-731/23 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 29 November 2023,

Nicoventures Trading Limited, established in London (United Kingdom),

British American Tobacco (Germany) GmbH, established in Hamburg (Germany),

British American Tobacco Italia SpA (BAT Italia), established in Rome (Italy),

British American Tobacco Polska Trading sp. z o.o., established in Warsaw (Poland),

British American Tobacco España SA, established in Madrid (Spain),

P.J. Carroll & Company Limited, established in Dublin (Ireland),

represented by M. Schonberg and L. Van den Hende, advocaten,

appellants,

the other parties to the proceedings being:

European Commission, represented by F. van Schaik and H. van Vliet, acting as Agents,

defendant at first instance,

supported by:

French Republic, represented by M. de Lisi, B. Fodda and B. Travard, acting as Agents,

intervener in the appeal,

* Language of the case: English

THE COURT (Second Chamber),

composed of K. Jürimäe (Rapporteur), President of the Chamber, K. Lenaerts, President of the Court, acting as Judge of the Second Chamber, F. Schalin, M. Gavalec and Z. Csehi, Judges,

Advocate General: N. Emiliou,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 12 June 2025,

gives the following

Judgment

1 By their appeal, Nicoventures Trading Limited, British American Tobacco (Germany) GmbH, British American Tobacco Italia SpA (BAT Italia), British American Tobacco Polska Trading sp. z o.o., British American Tobacco España SA and P.J. Carroll & Company Limited seek to have set aside the order of the General Court of the European Union of 20 September 2023, *Nicoventures Trading and Others* v *Commission* (T-706/22, 'the order under appeal', EU:T:2023:579), by which the General Court dismissed as inadmissible their action for annulment of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products (OJ 2022 L 283, p. 4; 'the delegated directive').

Legal context

Directive 2014/40/EC

2 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1) lays down rules for the placing of tobacco products on the market.

3 Article 2 of that directive, entitled 'Definitions', provides:

'For the purposes of this Directive, the following definitions shall apply:

…

(18) "ingredient" means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

…

(25) "characterising flavour" means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

…

(28) "substantial change of circumstances" means an increase of the sales volumes by product category by at least 10% in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5% of total sales of tobacco products at [European] Union level;

…'

4 Article 5 of the Directive, entitled 'Reporting of ingredients and emissions', states:

'1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities the following information by brand name and type:

(a) a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco products;

…

For a new or modified tobacco product the information required under this Article shall be submitted prior to the placing on the market of those products.

…

6. Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Member States shall also require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015. Member States shall provide any other sales volume data that is available to them.

7. All data and information to be provided to and by Member States under this Article and under Article 6 shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the [European] Commission and other Member States have access to that information for the purposes of applying this Directive. …'

5 Article 7 of Directive 2014/40, entitled ‘Regulation of ingredients’, provides:

‘1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

…

7. Member States shall prohibit the placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine.

…

12. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

…’

6 Article 9 of the Directive concerns the general warning and information message which must appear on unit packets and on the outside packaging of tobacco products for smoking. Article 10 of the Directive lays down the obligations relating to the health warnings which must be given on each unit packet and on any outside packaging of those products.

7 Article 11 of Directive 2014/40, entitled ‘Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco’, states:

‘1. Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. …

…

6. The Commission shall adopt delegated acts in accordance with Article 27, to withdraw the possibility of granting exemptions for any of the particular product categories referred to in paragraph 1 if there is a substantial change of circumstances as established in a Commission report for the product category concerned.’

8 Article 19 of the Directive, entitled ‘Notification of novel tobacco products’, provides:

‘1. Member St[at]es shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with Article 5. …

2. … Member States shall make all information received pursuant to this Article available to the Commission.

3. Member States may introduce a system for the authorisation of novel tobacco products. …

…'

The delegated directive

9 Article 1 of the delegated directive provides:

'Directive [2014/40] is amended as follows:

(1) Article 7(12) is replaced by the following:

"12. Tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

For the purposes of the first subparagraph, 'heated tobacco product' means a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking."

(2) Article 11 is amended as follows:
(a) the heading is replaced by the following:

"Article 11

Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products";
(b) in paragraph 1, the first subparagraph is replaced by the following:

"Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products as defined in Article 7(12), second subparagraph, from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. In that event, and in addition to the general warning provided for [in] Article 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Annex I. The general warning specified in Article 9(1) shall include a reference to the cessation services referred to in Article 10(1), point (b)."'

Background to the dispute

10 The background to the dispute is set out in paragraphs 2 to 6 of the order under appeal. For the needs of the present appeal, it may be summarised as follows.

11 The British American Tobacco group ('the BAT group'), to which the appellants belong, manufactures and markets tobacco products, including heated tobacco products. One of the appellants, Nicoventures Trading, was established in the course of 2011 within the BAT group in order to focus exclusively on the development and commercialisation of innovative non-combustible products, which include heated tobacco products. Nicoventures Trading sells the BAT group's heated tobacco products to other companies within the group, including the other appellants. Those latter companies distribute or intend to distribute the products of Nicoventures Trading on the markets of 14 Member States.

12 On 15 June 2022, the Commission, in accordance with Directive 2014/40, published a report establishing a substantial change of circumstances for heated tobacco products.

13 Following that report, the Commission adopted the delegated directive on the basis of Article 7(12) and Article 11(6) of Directive 2014/40. As of 23 October 2023, when the measures necessary for compliance with the delegated directive were to be applied by the Member States, heated tobacco products are no longer exempted from the prohibitions in respect of flavourings set out in Article 7(1) and (7) of Directive 2014/40. In addition, as of that same date, non-prohibited heated tobacco products for smoking are subject to the same labelling and packaging constraints as other non-exempted tobacco products for smoking.

Proceedings before the General Court and the order under appeal

14 By application lodged at the Registry of the General Court on 16 November 2022, the appellants brought an action for annulment of the delegated directive.

15 Taking the view that the appellants were neither directly nor individually concerned by the delegated directive, for the purposes of the fourth paragraph of Article 263 TFEU, the Commission raised an objection of inadmissibility on 17 January 2023.

16 By the order under appeal, the General Court upheld the plea of inadmissibility and dismissed the action as inadmissible.

17 At the outset, the General Court found in paragraphs 13 and 14 of the order that the delegated directive was a regulatory act, within the meaning of the fourth paragraph of Article 263 TFEU, which, in Article 2 thereof, provided for implementing measures, namely transposing measures that the Member States were to adopt. The General Court thereby inferred that the action for annulment did not fall within the third situation referred to in the fourth paragraph of Article 263 TFEU, namely that any person may institute proceedings against regulatory acts which are of direct concern to them and which do not entail implementing measures. It also found that since the appellants were not the addressees of the delegated directive, the action for annulment could not fall within the first situation referred to in that provision, according to which any person may institute proceedings against an act addressed to that person. Consequently, the General Court found that it was necessary to assess whether the appellants fell within the second situation provided for in that provision, namely whether they were directly and individually concerned by the delegated directive.

18 As regards the condition that an applicant must be directly concerned by the contested act, the General Court found in paragraphs 24, 26 and 28 of the order under appeal, after referring to the relevant case-law of the Court of Justice, that the legal situation of operators which, like the

appellants, market or intend to market heated tobacco products with a characterising flavour, was affected by the delegated directive in that the marketing of those products would become unlawful following the adoption thereof. Those operators would also be obliged to display the same health warnings on the packaging of non-prohibited heated tobacco products for smoking as those that had to appear on the packaging of certain other tobacco products for smoking.

19 The appellants would thus be subject to a prohibition to market heated tobacco products with a characterising flavour and to obligations arising directly from the delegated directive, irrespective of whether that directive entailed implementing measures, namely transposition measures that the Member States had to adopt. In the case at hand, the transposing measures provided for in that directive were necessary only for the implementation in full of the prohibition and obligations in question in the laws of the Member States, without the Member States having any discretion of their own, since the delegated directive did not leave any discretion to the Member States in respect of that prohibition and those obligations.

20 Accordingly, the General Court held that the appellants were to be regarded as being directly concerned by that directive and that none of the arguments put forward by the Commission could call those assessments into question.

21 As regards the condition that the contested measure must be of individual concern to an applicant, the General Court, in paragraph 36 of the order under appeal, first observed, relying, inter alia, on the judgment of 15 July 1963, *Plaumann* v *Commission* (25/62, EU:C:1963:17), that measures of general application may be of individual concern to certain natural or legal persons, and be thus in the nature of a decision in their regard, where, in particular, those acts affect them by reason of certain attributes peculiar to them or by reason of a factual situation which differentiates them from all other persons and thereby distinguishes them individually in the same way as the addressee.

22 Referring to paragraph 18 of the judgment of 18 May 1994, *Codorniu* v *Council* (C-309/89, EU:C:1994:197), the General Court stated in paragraph 37 of the order under appeal that the general applicability and, thus, the legislative nature of a measure were not called into question by the fact that it was possible to determine more or less exactly the number or even the identity of the persons to whom it applied at any given time, as long as it was established that it applied to them by virtue of an objective legal or factual situation defined by the measure in question in relation to its purpose.

23 The General Court then examined the arguments made by the appellants to demonstrate that they were individually concerned by the delegated directive.

24 First, the General Court held in paragraph 45 of the order under appeal that the sole fact that the operators which had made a declaration or notification, provided for respectively in Articles 5 and 19 of Directive 2014/40, or held an authorisation by virtue of a system established under Article 19(3) thereof, were identifiable at the time of the adoption of the delegated directive could not suffice to establish that they were individually concerned where that delegated directive applied by virtue of general and abstract considerations. According to the General Court, the Commission was not required to take particular account of their situation when adopting the delegated directive.

25 Second, the General Court, in paragraph 46 of the order under appeal, rejected the argument based on the small number of undertakings affected by the delegated directive since the number of natural or legal persons affected by such an act was not decisive in that regard.

26 Third, the General Court acknowledged in paragraph 47 of the order under appeal that the absolute prohibition on marketing heated tobacco products with characterising flavours as a result of the delegated directive would necessarily have the effect of calling into question the authorisations to market such tobacco products held by some of the appellants. However, it held in paragraphs 47 and 49 of the order under appeal that such authorisations, granted without exclusivity, could not be regarded as differentiating the position of the holders of those authorisations and distinguishing that position individually with regard to the delegated directive as if they had been its addressees. Moreover, according to the General Court, the authorisations in question did not confer on their holders rights comparable to those enjoyed by the applicants and appellants in the cases giving rise to the judgments of 17 January 1985, *Piraiki-Patraiki and Others* v *Commission* (11/82, EU:C:1985:18); of 18 May 1994, *Codorniu* v *Council* (C-309/89, EU:C:1994:197); of 13 March 2008, *Commission* v *Infront WM* (C-125/06 P, EU:C:2008:159); and of 27 February 2014, *Stichting Woonpunt and Others* v *Commission* (C-132/12 P, EU:C:2014:100).

27 Fourth, the General Court found in paragraph 51 of the order under appeal that the circumstance that manufacturers and importers of heated tobacco products with a characterising flavour are not, having regard to the delegated directive, in the same situation as the industries upstream and downstream in the production and distribution chain of the products at issue was irrelevant to the question whether the appellants belong to a limited class. The appellants, for the purpose of demonstrating that they were individually concerned by the delegated directive, had to prove not that they were affected in a way which was different from other operators, but that they were concerned by reason of an attribute or a factual situation which was peculiar to them and which distinguished them in the same way as the addressee of a decision.

28 The General Court, in paragraph 52 of the order under appeal, inferred from all of those considerations that the authorisations, declarations and notifications on which the appellants had relied did not make it possible to prove that they were individually concerned by the delegated directive.

29 In paragraphs 54 and 55 of the order under appeal, the General Court, responding to the appellants' argument that the directive had a substantial effect on their competitive position, found that the fact that certain operators were more affected economically by a measure of general application than others was not sufficient to distinguish them individually from all other operators, since the application of that measure takes effect by virtue of an objectively determined situation. In addition, the mere fact that natural or physical persons may lose a major source of income as a result of new legislation did not prove that they were in a specific situation and was not sufficient to establish that that legislation applied to them individually, those persons having to adduce proof of circumstances which made it possible to consider that the harm allegedly suffered was such as to distinguish them individually from all other economic operators concerned by that legislation in the same way as they were.

30 Consequently, the General Court held that the appellants were not justified in claiming that they were individually concerned by the delegated directive and that the action had therefore to be dismissed as inadmissible.

Forms of order sought and procedure before the Court of Justice

31 By their appeal, the appellants claim that Court of Justice should:

– set aside the order under appeal;

– to the extent that the Court of Justice considers that the state of the proceedings so permits, reject the plea of inadmissibility, declare the action at first instance admissible, and refer the case back to the General Court to rule on the substance, and

– order the Commission to pay the costs, including those incurred before the General Court.

32 The Commission contends that the Court should:

– dismiss the appeal, and

– order the appellants to pay the costs.

33 By order of the President of the Court of Justice of 25 April 2024, *Nicoventures Trading and Others* v *Commission* (C-731/23 P, EU:C:2024:380), the French Republic was granted leave to intervene in support of the form of order sought by the Commission. It contends that the Court should dismiss the appeal in its entirety and thus confirm that the action is inadmissible.

The appeal

34 In support of their appeal, the appellants rely on a single ground of appeal in which they allege that the General Court erred in law in the application to their situation of the condition that an applicant must be individually concerned by the contested act. The ground of appeal is divided into two separate parts, alleging errors of law, respectively, in the evaluation of the factors relied on by the appellants to show that they were individually concerned by the delegated directive, and in the assessment of the legal test of a 'substantial effect on market position'.

The first part of the single ground of appeal

Arguments of the parties

35 The first part of the single ground of appeal concerns paragraphs 45 to 52 of the order under appeal. The appellants complain that the General Court erred in law when assessing the legal significance of the factors on which they had relied before it and when holding that those factors were insufficient to establish that they were individually concerned by the delegated directive.

36 They argue that the General Court thus erred in law by assessing each of those factors separately and individually and by examining whether each of them was sufficient in and of itself to establish that the appellants were individually concerned by the delegated directive. Such an approach is not consistent with the case-law that requires identification of 'the body of evidence' or 'a set of factual and legal factors' capable of distinguishing the applicant individually.

37 In the first place, contrary to the General Court's findings in paragraph 45 of the order under appeal, the fact that the appellants, through the declarations and product notifications made respectively under Articles 5 and 19(1) of Directive 2014/40, were identifiable to the Commission at the time of the adoption of the delegated directive is of pertinence.

38 In the second place, the appellants criticise paragraph 46 of the order under appeal on the ground that it follows from recent case-law that the significance of an applicant's market position, although not sufficient in itself to establish that it is individually concerned by the contested measure, is nevertheless relevant in so far as it forms part of a set of factors that constitute a particular situation which differentiates that applicant. That is also the situation in the present case, given the significance of the BAT group's position in the EU market for heated tobacco products.

39 Furthermore, the General Court's finding in paragraph 51 of the order under appeal, that manufacturers of heated tobacco products cannot be distinguished from other operators active in the production and distribution chain of the products at issue, is unfounded as a matter of law. The fact that a measure may also affect other operators cannot mean that the measure may not be of individual concern to an operator that is impacted in a direct and significant manner.

40 In the present case, the various operators involved in the production and distribution chain of the products at issue are distinguished by means of the notification system established under Article 5 and Article 19(1) of Directive 2014/40. That system requires notification only by the manufacturer or importer of the product concerned and not by a downstream or upstream supply chain operator. The existence of another manufacturer or producer cannot be relied on in that regard to exclude the appellants from being individually concerned by the delegated directive.

41 In the third place, the General Court erred in law in paragraphs 47 to 50 of the order under appeal by failing to give sufficient weight to the marketing authorisations obtained by certain of the appellants prior to the adoption of the delegated directive.

42 In that regard, first, the appellants claim that it is incorrect to state that the delegated directive has the same effects on all operators, whether or not they hold a marketing authorisation, since those which have an authorisation, unlike the others, will lose it. Second, the pre-existing rights held before the adoption of that directive do not necessarily have to be exclusive in order to find that the appellants are individually concerned by it, in accordance with the judgments of 13 March 2008, *Commission* v *Infront WM* (C-125/06 P, EU:C:2008:159), and of 27 February 2014, *Stichting Woonpunt and Others* v *Commission* (C-132/12 P, EU:C:2014:100). Third, such pre-existing rights need not have been 'acquired indefinitely' in order to be relevant in that regard.

43 The Commission contends that the first part of the single ground of appeal is unfounded.

44 The fact that the General Court examined the arguments raised at first instance in a systematic and structured manner does not mean that it failed to take account of the 'body of evidence' required by the case-law referred to by the appellants. The Commission also disputes the suggestion that, if the General Court had taken the approach advocated by the appellants, it would have found that they were individually concerned since each of the factors they raised was clearly relevant and of significance.

45 As a preliminary point, the Commission criticises the appellants for giving the impression that they had relied on a large number of factors, which should have been assessed jointly by the General Court. The appellants' arguments in the application at first instance were limited to maintaining, in essence, that they have a special status. First, because they form a closed class of economic operators, identifiable, and indeed identified, when the delegated directive was adopted owing to the declarations and notifications made under Articles 5 and 19 of Directive 2014/40 respectively. Second, because the delegated directive is liable to have a substantial effect on their market position. According to the Commission, the General Court explained in convincing fashion why those two arguments did not serve to establish that the appellants are individually concerned by the delegated directive.

46 As regards the first argument, the General Court was right to state, in paragraph 43 of the order under appeal, that the requirements laid down in Articles 5 and 19 of Directive 2014/40 are general and abstract and are applicable to all operators placing or intending to place a tobacco product on the market. Those requirements cannot be regarded as differentiating the position of the holders of authorisations and distinguishing that position individually with regard to the delegated directive as if they had been its addressees.

47 In that context, first, the appellants' arguments that it was possible to identify a closed group of economic operators when the delegated directive was adopted are ineffective.

48 Second, the Commission is of the view that the appellants misrepresent the content of paragraph 46 of the order under appeal in that, in contrast to what they claim, the General Court referred in that paragraph not to the appellants' market share, but to the number of undertakings affected by the delegated directive. Those two criteria are different, and irrelevant, for determining whether the appellants are individually concerned by that directive.

49 The appellants also misrepresent paragraph 51 of the order under appeal in that, contrary to what they claim, the General Court did not state in that paragraph that manufacturers of heated tobacco products cannot be distinguished from other operators active in the distribution or supply chain of the products at issue.

50 The argument made by the appellants, that the existence of another manufacturer or producer cannot be relied on to rule the appellants out as being individually concerned by the delegated directive, is ineffective since the General Court did not rely on such a finding in the order under appeal.

51 Third, the argument that the General Court, in paragraphs 47 to 50 of the order under appeal, failed to give sufficient weight to the marketing authorisations held by the appellants should be rejected.

52 First, the General Court did not find that the delegated directive had the same effects for all operators. The appellants' argument to the contrary is therefore ineffective. Second, the case-law relied on by the appellants in support of that argument is irrelevant. Accordingly, the judgment of 13 March 2008, *Commission* v *Infront WM* (C-125/06 P, EU:C:2008:159), concerns an action against a measure of general application brought by persons who held acquired rights, whereas the judgment of 27 February 2014, *Stichting Woonpunt and Others* v *Commission* (C-132/12 P, EU:C:2014:100), is an example of an action brought by legal persons against an act calling into question a Commission decision relating to a State aid scheme from which they benefited.

53 The General Court, therefore, did not err in law in holding in paragraph 47 of the order under appeal that the authorisations at issue did not confer on their holders rights comparable to those enjoyed by the appellants in the cases referred to in the preceding paragraph above. In the present case, the alleged consequence of the delegated directive might consist of nothing but a 'loss of an opportunity to make a profit', in the sense of vain hopes, that is to say, a loss of an opportunity that was available to any person that was interested in producing or trading heated tobacco products.

54 The French Republic endorses all of the Commission's arguments. It adds that the delegated directive applies to all operators that have been duly authorised to place heated tobacco products on the market, including the appellants' competitors. Moreover, it is natural that only a small number of operators will initially invest in a newly emerging market. That does not necessarily mean, however, that the specific situation of the appellants, whose sole distinguishing feature is the fact that they were early operators on that market, is such that the delegated directive distinguishes them individually, in the same way as an addressee thereof.

Findings of the Court

55 The first part of the single ground of appeal alleges that the General Court erred in law in its assessment of the factors put forward by the appellants to show that they belonged to a closed category of economic operators that were identified or identifiable when the delegated directive was adopted, and that they were therefore individually concerned by that directive, in terms of the fourth paragraph of Article 263 TFEU.

56 The arguments made by the appellants relate, in particular, to paragraphs 45 to 52 of the order under appeal, in which the General Court examined whether the declarations and notifications, made respectively under Articles 5 and 19 of Directive 2014/40, and the holding of marketing authorisations, obtained in the Member States which had established an authorisation system on the basis of Article 19(3) of that directive, were sufficient to distinguish them individually in the same way as the addressee of a decision.

57 In that regard, it is clear from settled case-law that persons other than those to whom a decision is addressed may claim to be individually concerned only if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and, by virtue of those factors, distinguishes them individually just as in the case of the person addressed by such a decision (see, inter alia, judgments of 15 July 1963, *Plaumann* v *Commission*, 25/62, EU:C:1963:17, p. 107; of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 93; and of 31 January 2023, *Commission* v *Braesch and Others*, C-284/21 P, EU:C:2023:58, paragraph 51).

58 In that context, the possibility of determining more or less precisely the number, or even the identity, of the persons to whom a measure applies by no means implies that it must be regarded as being of individual concern to them as long as that measure is applied by virtue of an objective legal or factual situation defined by it (judgments of 16 March 1978, *Unicme and Others* v *Council*, 123/77, EU:C:1978:73, paragraph 16; of 22 November 2001, *Antillean Rice Mills* v *Council*, C-451/98, EU:C:2001:622, paragraph 52; and of 12 July 2022, *Nord Stream 2* v *Parliament and Council*, C-348/20 P, EU:C:2022:548, paragraph 157).

59 However, it is also clear from settled case-law that where a measure affects a group of persons who were identified or identifiable when that measure was adopted by reason of criteria specific to the members of the group, those persons may be individually concerned by that measure inasmuch as they form part of a limited class of economic operators (see, to that effect, judgments of 17 January 1985, *Piraiki-Patraiki and Others* v *Commission*, 11/82, EU:C:1985:18, paragraph 31; of 22 June 2006, *Belgium and Forum 187* v *Commission*, C-182/03 and C-217/03, EU:C:2006:416, paragraph 60; of 13 March 2008, *Commission* v *Infront WM*, C-125/06 P, EU:C:2008:159, paragraph 71; and of 12 July 2022, *Nord Stream 2* v *Parliament and Council*, C-348/20 P, EU:C:2022:548, paragraph 158). That may be the case particularly when the measure alters rights acquired by the individual prior to its adoption (judgments of 13 March 2008, *Commission* v *Infront WM*, C-125/06 P, EU:C:2008:159, paragraph 72, and of 27 February 2014, *Stichting Woonpunt and Others* v *Commission*, C-132/12 P, EU:C:2014:100, paragraph 59).

60 Accordingly, in order to be individually concerned as a member of a limited class of persons, it is necessary, first, for an applicant to show that it was identified, or at least capable of being so, when the contested act was adopted, by the author of that act, on the basis of sufficiently exact information which that author was in a position to obtain (see, to that effect, judgment of 17 January 1985, *Piraiki-Patraiki and Others* v *Commission*, 11/82, EU:C:1985:18, paragraph 31), and, second, that that applicant has specific characteristics in comparison with other persons to whom that act is intended to apply.

61 In the present case, the effect of the delegated directive is, first, to prohibit the marketing of heated tobacco products which contain characterising flavours and of those with a flavour in one of their components and, second, to subject heated tobacco products for smoking to the same labelling requirements as cigarettes, roll-your-own tobacco and water-pipe tobacco.

62 Accordingly, as the General Court found in paragraphs 28 and 30 of the order under appeal, the marketing in question became unlawful from 23 October 2023, the date when provisions had to have been adopted by the Member States in order to comply with the delegated directive and began to apply. Consequently, the appellants which marketed heated tobacco products containing characterising flavours or a flavour in one of their components were deprived of the possibility of marketing such products from that date.

63 Furthermore, the delegated directive also had the effect, from 23 October 2023, of altering the regime under which the appellants had been able, until that date, to market their heated tobacco products since the conditions for pursuing their activities were made less favourable than previously, owing in particular to the new obligations on labelling now imposed on those products.

64 First, as the Advocate General observed, in essence, in points 163 and 164 of his Opinion, that new regime is the consequence of a ‘substantial change of circumstances’, within the meaning of Article 2(28) of Directive 2014/40, which was established by the Commission, in accordance with that provision, on the basis of the sales volume of the products at issue, as declared by the manufacturers and importers pursuant to the obligation laid down in Article 5(6) of that directive.

65 Second, since heated tobacco products are novel tobacco products, their placing on the market by the appellants was necessarily preceded, pursuant to Article 5 and Article 19(1) of that directive, by a notification to the competent authorities of the Member States. That notification was

accompanied, in particular, by the list of ingredients used in the manufacture of those products, which include additives such as characterising flavours, with the information communicated at that time being made available to the Commission under Article 19(2) of Directive 2014/40.

66 Furthermore, that placing on the market was, as necessary, subject to an authorisation by those Member States which had chosen to avail themselves of the possibility given to them in that regard by Article 19(3) of that directive.

67 In those circumstances, it must be held, first, that the appellants form part of a limited class of economic operators which were identified or identifiable by the Commission when the delegated directive was adopted, owing to the finding, before the adoption of that directive, of a 'significant change of circumstances', the requirement for triggering the Commission's delegated power established in both Article 7(12) and Article 11(6) of Directive 2014/40, and owing to the notification obligations and authorisation decisions referred to in paragraphs 65 and 66 above.

68 Second, the appellants are particularly affected by the new prohibitions and obligations laid down by the delegated directive since it had the effect of altering, from 23 October 2023, the regime for the marketing of heated tobacco products from which they had benefited until that date since the conditions for the pursuit of their activities were made less favourable than previously, in particular in view of the fact that the sale of heated tobacco products with characterising flavours has simply been prohibited by the delegated directive. Operators active on that market, such as the appellants, have therefore definitively lost their right to market those products and no other operator will be able to do so in the future.

69 Accordingly, the General Court erred in law by holding in paragraph 47 of the order under appeal that the authorisations granted to certain of the appellants under Directive 2014/40 could not be regarded as differentiating the position of the holders of those authorisations and distinguishing that position individually with regard to the delegated directive as if they had been its addressees, and by concluding, in paragraph 52 of that order, that the authorisations, declarations and notifications on which the appellants relied before it did not make it possible to prove that they are individually concerned by the delegated directive.

70 As the Advocate General observed, in essence, in point 168 of his Opinion, the fact that the marketing authorisations at issue were non-exclusive, as referred to in paragraph 49 of the order under appeal, can have no bearing on the ability to distinguish the appellants individually. In fact, the relevant criterion in that regard lies in the alteration of rights acquired by the applicant prior to the adoption of the contested act (see, to that effect, judgment of 13 March 2008, *Commission* v *Infront WM*, C-125/06 P, EU:C:2008:159, paragraph 72), that is to say, in the fact of being the holder of a 'specific acquired right' (see, to that effect, order of 14 January 2021, *Sabo and Others* v *Parliament and Council*, C-297/20 P, EU:C:2021:24, paragraph 28), while that right need not be exclusive.

71 In the light of all those considerations, the first part of the single ground of appeal must be upheld and the order under appeal set aside, it not being necessary to examine the other arguments put forward by the appellants in support of that part.

The second part of the single ground of appeal

72 Since the success of the first part of the single ground of appeal leads to the order under appeal being set aside, it is not necessary to examine the second part of that ground of appeal, which cannot result in the order being set aside to a greater extent.

The action before the General Court

73 In accordance with the second sentence of the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the decision of the General Court is set aside, the Court of Justice may itself give final judgment in the matter, where the state of the proceedings so permits.

74 In the present case, while the Court of Justice is not in a position, at this stage of the proceedings, to rule on the merits of the action before the General Court, it does, however, have the necessary information to give a final ruling on the plea of inadmissibility raised by the Commission at first instance.

75 In support of the plea of inadmissibility, the Commission submits that the appellants are neither directly nor individually concerned by the delegated directive.

76 In the first place, in the absence of any specific challenge by the parties in that regard, the Court of Justice endorses the General Court's findings, set out in paragraphs 27 to 33 of the order under appeal, concerning the question of whether the appellants are directly concerned by the delegated directive.

77 In the second place, it follows from the considerations set out in paragraphs 61 to 68 above that the appellants in the present case are individually concerned by the delegated directive.

78 It follows that the action for annulment brought by the appellants before the General Court must be found to be admissible.

79 The case is to be referred back to the General Court for a ruling on the merits of the action for annulment.

Costs

80 Since the case is to be referred back to the General Court, the costs relating to the present proceedings must be reserved.

On those grounds, the Court (Second Chamber) hereby:

1. **Sets aside point 1 of the operative part of the order of the General Court of the European Union of 20 September 2023, *Nicoventures Trading and Others* v *Commission* (T-706/22, EU:T:2023:579);**

2. **Finds the action for annulment brought by Nicoventures Trading Limited, British American Tobacco (Germany) GmbH, British American Tobacco Italia SpA (BAT Italia), British American Tobacco Polska Trading sp. z o.o., British American Tobacco España SA and P.J. Carroll & Company Limited against Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products to be admissible;**

3. **Refers the case back to the General Court of the European Union for a ruling on the merits of the action for annulment referred to in point 2 of the present operative part;**

4. **Reserves the costs.**

Jürimäe Lenaerts Schalin

Gavalec Csehi

Delivered in open court in Luxembourg on 18 December 2025.

A. Calot Escobar
Registrar

K. Jürimäe
President of the Chamber