THE HIGH COURT

JUDICIAL REVIEW

[2023] IEHC 669

Record No. 2022/1085 JR

Between:

PJ CARROLL & COMPANY LIMITED and NICOVENTURES TRADING LIMITED

Applicants

And

THE MINISTER FOR HEALTH, IRELAND and THE ATTORNEY GENERAL

Respondents

And

PHILIP MORRIS LIMITED, PHILIP MORRIS PRODUCTS SA and PHILIP MORRIS MANUFACTURING & TECHNOLOGY BOLOGNA SPA

Notice Parties

Judgment of Mr Justice Cian Ferriter delivered this 11th day of September 2023

Introduction

1. In these proceedings, the applicants challenge the State's transposition of an EU delegated directive concerning tobacco regulation, being Commission delegated directive (EU) 2022/2100 (the "delegated directive"). The applicants contend that the delegated directive is invalid as a matter of EU law on the basis that the European Commission ("the Commission") in passing the delegated directive exceeded the powers delegated to it under under the provisions of Directive 2014/40/EU (the "Tobacco Products Directive" or "TPD"), contrary to Article 290 TFEU.

2. The terms of the delegated directive were transposed into Irish law, subsequent to the commencement of these proceedings, by S.I .335 of 2023 (the European Union (Manufacture,

Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023) ("the 2023 Regulations"), which amended the European Union (Manufacture, Presentation and Sale of Tobacco Related Products) Regulations 2016 (SI 271 of 2016) ("the 2016 Regulations") which in turn had transposed the provisions of the Tobacco Products Directive into Irish law. The 2023 Regulations amend the 2016 Regulations by providing that certain exemptions from prohibition on ingredients and certain packaging information and warning requirements (found in articles 7(12) and 11(6) of the TPD) do not apply to "heated tobacco products". "Heated tobacco products" ("HTPs") are defined in the delegated directive as essentially involving products which are "*heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s)".* The 2023 Regulations stand to come into operation on 23 October 2023.

3. The principal relief sought in these judicial review proceedings is a declaration that the 2023 Regulations transposing the delegated directive into Irish law are *ultra vires* the powers conferred by s. 3 of the European Communities Act 1972 (as amended) and contrary to Article 15.2.1 of the Constitution. The applicants seek that declaration on the basis that the delegated directive is invalid as a matter of EU law and, therefore, the 2023 Regulations purporting to implement the delegated directive are also invalid. Accordingly, the essential issue in the proceedings is the validity or otherwise of the delegated directive.

4. The applicants invite the Court to request a preliminary ruling from the Court of Justice of the European Union (the "CJEU") as to the validity of the delegated directive on the basis that the determination of that question is essential to the determination of these proceedings, it being common case that this Court has no jurisdiction to declare an EU act invalid.

The parties

5. The applicants are part of the British American Tobacco group of companies (*"*BAT*"*). BAT says that, while historically its main focus was on traditional tobacco products, it is increasingly focused on the development and sale of *"non-combustible alternatives to conventional cigarettes for adult smokers who would otherwise continue to smoke"*. This includes the development and sale of heated tobacco products both globally and within the EU.

6. The applicants' heated tobacco products are said by them to be non-combustible products which do not involve the burning of tobacco; rather, the tobacco in the heated tobacco product

device is heated. BAT's heated tobacco device is marketed in the EU under the brand named *"glo"*. A user operates glo by inserting into the device a specially designed rod which the applicants say contains approximately half of the tobacco of a conventional cigarette. This tobacco rod is then heated without combustion, producing a nicotine-containing aerosol which the user inhales and exhales. The glo product is currently being sold in 14 countries within the EU. The applicants maintain that heated tobacco products, while containing tobacco, have a reduced risk profile relative to cigarettes.

7. The first named applicant is responsible for the importation, distribution and sale of BAT's tobacco products in Ireland. The first named applicant plans to market and sell heated tobacco products in Ireland, including those with "characterising flavours" (a concept defined in the TPD) and/or with components containing flavourings. For ease, I will refer to heated tobacco products with characterising flavours and/or with components containing flavourings as *"flavoured heated tobacco products"* or *"flavoured HTPs"*.

8. The second named applicant is a UK company which sells BAT's heated tobacco products to other companies in the BAT group which then act as the second named applicant's distributors in the EU Member State markets in which they operate. The second named applicant plans to supply the first named applicant with flavoured heated tobacco products for marketing and sale in Ireland.

9. The notice parties are all companies in the Philip Morris International group ("PMI"), another major international tobacco group. Together, BAT and PMI are responsible for the sale of virtually all of the HTPs in the EU. The notice parties were joined as notice parties to the proceedings by order of this Court of 22 March 2023, following a contested application. PMI has a significant market share of the HTP market in the EU. PMI currently has a significant commercial presence in Ireland through its conventional tobacco products and says that it has plans to market HTPs in Ireland in the future.

10. For ease, I will refer to the respondents as *"the State"*.

Standing

11. While the question of the applicants' standing to maintain those proceedings was put in issue in the State's opposition papers, that objection was not pursued at the hearing.

12. The first named applicant says it has invested significantly in the commercialisation of e-cigarettes in Ireland and currently holds approximately 10% of the Irish market for e-cigarettes. It has begun taking steps to commercialise heated tobacco products in Ireland, including flavoured heated tobacco products. It made pre-budget submissions to the Irish Government in relation to the tax treatment of, *inter alia*, heated tobacco products in 2021 and 2022. On 1 November 2020, the second named applicant submitted the requisite product notifications under regulation 24 of the 2016 Regulations to the *"EU Common Entry Gate"* system thereby paving the way for the introduction by it of HTPs in Ireland. The six-month clearing period under the product notification system expired on 1 May 2023.

13. I am satisfied that the applicants have standing to maintain these proceedings. They have taken proactive steps towards distributing and selling heated tobacco products for sale in the Irish market. The transposition of the delegated directive "*has or is imminently in danger of affecting* [the applicants'] *interests so as to cause or potentially cause injury or prejudice*" to use the formulation of Clarke and O'Malley JJ in *Grace v. An Bord Pleanála* [2017] IESC 10 at para. 5.4.

14. PMI says that the transposition by Ireland of the delegated directive will severely impact its plan to market HTPs in Ireland, and that the implementation of the delegated directive across the EU will have a seismic effect on a major part of its European business. I accept also that the notice parties have sufficient standing to join in support of the applicants' case in the circumstances.

The Tobacco Products Directive

15. In order to put the issues in these proceedings in context, it is necessary to set out the background to the TPD and the provisions of the TPD of most relevance to the issues in these proceedings.

16. The TPD was enacted on 3 April 2014 and its measures were required to be brought into force in member states by 20 May 2016. The TPD replaced an earlier directive dealing with tobacco products, being Directive 2001/37/EC.

17. The objective of the TPD is set out in article 1 as being to approximate the laws, regulations and administrative provisions of the Member States concerning a wide range of aspects of tobacco products including their ingredients and emissions; aspects of labelling, packaging and health warnings; the prohibition of tobacco for oral use; cross-border distance sales; the notification of novel tobacco products and the placing on the market and labelling of e-cigarettes and herbal cigarettes. All of this is "*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')*".

18. The definition of the "tobacco products" to which the TPD is directed is very wide: 'tobacco products' are defined in article 2(4) as "*products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not*".

19. The health concerns in relation to tobacco products, and the consequent need to reduce smoking among young people, animate the provisions of the TPD. This is reflected in recital 8 which notes that "*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*". As we have seen, health protection is one of the objectives of the directive as set out in in article 1.

20. Recital 19 states that "*Considering this Directive's focus on young people, tobacco products other than cigarettes and roll-your-own tobacco, should be granted an exemption from certain requirements relating to ingredients as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people*." This policy choice is reflected in article 7 which is headed "regulation of ingredients", in particular in article 7(1), (7) and (12).

21. Article 7(1) provides that *"Member States shall prohibit the placing on the market of tobacco products with a characterising flavour."* Article 7(7) provides that Member States shall prohibit the placing on the market of tobacco products containing flavourings in any of their components. Article 7(12) (a key provision in issue in these proceedings) then provides that:

"*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.*"

22. The term "substantial change of circumstances" is defined in article 2(28) as follows:

> "'*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 Union level*"

23. Certain of the provisions of the TPD are addressed only to tobacco products for smoking while other provisions are addressed to tobacco products more generally. "Tobacco products for smoking" are defined in article 2(9) as "tobacco products other than a smokeless tobacco product". "Smokeless tobacco product" is defined in article 2(5) as "a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use". So, for example, article 9 addresses "General warnings and information messages on tobacco products for smoking" and article 10 addresses "Combined health warnings for tobacco products for smoking".

24. Article 11, which is headed "Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco", provides for the possibility of exemption from a number of the labelling/warning obligations found in articles 9 and 10 for certain tobacco products for smoking. It states in article 11(1) that "*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. 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)(b)."

25. As with article 7(12), article 11(6) provides a delegated power to the Commission to withdraw exemptions. It provides that "*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.*" This provision is also in issue in these proceedings.

26. The policy behind this provision is reflected in recital 26 which states:

> *"For tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers and small groups of the population, it should be possible to continue to grant an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people. The labelling of these other tobacco products should follow rules that are specific to them. The visibility of health warnings on smokeless tobacco products should be ensured. Health warnings should, therefore, be placed on the two main surfaces of the packaging of smokeless tobacco products. As regards waterpipe tobacco, which is often perceived as less harmful than traditional tobacco products for smoking, the full labelling regime should apply in order to avoid consumers being misled."*

27. Importantly, the TPD seeks to regulate novel tobacco products. Article 2(14) defines 'novel tobacco product' as meaning "*a tobacco product which: (a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and (b) is placed on the market after 19 May 2014*". The tobacco products itemised in article 2(14)(a) each have their own definition in article 2 TPD.

28. Recitals 34 and 35 provide as follows:

> *"(34) All tobacco products have the potential to cause mortality, morbidity and disability. Accordingly, their manufacture, distribution and consumption should be*

regulated. It is, therefore, important to monitor developments as regards novel tobacco products. Manufacturers and importers should be obliged to submit a notification of novel tobacco products, without prejudice to the power of the Member States to ban or to authorise such novel products.

(35) In order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive."

29. These policy choices are reflected in article 19 which is headed "Notification of novel tobacco products". It provides in article 19(1) that "*Member States 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*" and sets out the detailed information that must be notified in relation to such products including scientific studies on the addictiveness of the product, market research on the preferences of consumer groups such as young people and current smokers and a risk/benefit analysis of the products and their expected effects on initiation of tobacco consumption.

30. Significantly, article 19(4) provides that "*Novel tobacco products placed on the market shall respect the requirements of this Directive. Which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking."*

31. The various delegated powers granted to the Commission under the TPD, including those in articles 7(12) and 11(6), are addressed in recital 51 as follows: *"In order to ensure that this Directive is fully operational and to adapt it to technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission"* specifying *inter alia "withdrawing certain exemptions granted to tobacco products other than cigarettes and roll-your-own tobacco"* and *"adapting the health warnings".*

32. Recital 52 provides that "*the Commission should monitor the developments as regards the implementation and impact of this Directive and submit a report by 21 May 2021, and when necessary thereafter, in order to assess whether amendments to this Directive are necessary"* and states that such report should include information on *inter alia "market developments*

concerning novel tobacco products" and *"market developments that amount to a substantial change of circumstances*."

33. This is reflected in the terms of article 28. Article 28(1) addresses the requirement for the Commission (with the assistance of "scientific and technical experts") to submit a review report within a specified timeframe. Article 28(2) provides that the Commission in its review report on the application of the TPD must indicate, in particular, *"the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco related products"* with the Commission being obliged to pay special attention to, *inter alia*, *"(b) market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19; and (c) market developments which constitute a substantial change of circumstances"*.

Unsuccessful challenge to validity of TPD

34. A number of companies in the PMI group, and a BAT UK company, took a challenge to the validity of the TPD which was dealt with by the CJEU on a reference from the High Court of England and Wales (Case C-547/14 (EU:2016:325)) ("the TPD validity challenge"). The CJEU in a judgment given on 4 May 2016 comprehensively upheld the validity of the TPD and rejected *inter alia* a contention that the terms of article 7(12) were invalid as being themselves contrary to the provisions of article 290 TFEU. The provisions of article 290 will be considered in further detail below in the context of the challenge maintained in the proceedings before this court.

Commission's 2021 TPD review report

35. The difficulty of categorising heated tobacco products within the terms of the TPD had been adverted to in a Commission report dated 20 May 2021. This report was submitted by the Commission pursuant to its obligations under article 28(1) of the TPD which as already noted, imposes an obligation on the Commission to discuss *inter alia*, the elements of the TPD that should be reviewed given scientific and technical developments, including internationally agreed rules and standards on tobacco and related products.

36. Section 7 of that report is headed *"Novel Tobacco Products (Article 19) and Other Emerging Products"*. The report in this section noted that:-

> *"The TPD provisions for "Novel Tobacco Products" were designed to provide a wide regulatory net for new tobacco product categories rapidly entering the EU market. However, the date-based definition means that its provisions are not specific to the unique characteristics of certain new products."* (at p. 11)

37. The report also noted in this section that the use of flavours was challenging as they particularly appeal to young people and stated that:-

> *"Novel Tobacco Products are exempted from the ban on characterising flavours (Article 7(12)). The TPD gives scope for withdrawing this exemption, but there is a significant regulatory barrier – the Commission has to demonstrate a 'substantial change of circumstances'."*

38. The report noted that views differed over the extent to which HTPs negatively affect the individual user's health. It then noted that:-

> *"The application of TPD provisions to Novel Tobacco Products depends on whether these products are defined as a smokeless tobacco product or a tobacco product for smoking. A smokeless tobacco product is defined as lacking a combustion process. This is a challenge for regulators as the principle of combustion is ambiguous, leading to Member States classifying certain products in a divergent manner… Moreover, without flexibility to define new product categories it is challenging to apply rules developed for existing categories to Novel Tobacco Products, as they do not necessarily respond to the distinct properties of the new products."*

39. In the conclusion of this section, it is noted that:-

> *"The EU regulatory framework does not currently address all Novel Tobacco and emerging products, nor provide flexibility to address rapid product developments. HTPs should be monitored closely as they pose specific regulatory challenges, including health warnings, use of flavours and interaction with devices."*

The process leading to the delegated directive

40. On 15 June 2022, the Commission published a report pursuant to article 28(2) TPD entitled *"Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU"* (document COM (2022) 279 final). This report concluded that a substantial change of circumstances in relation to heated tobacco products had been made out on the application of the criteria stipulated in article 28(2) TPD.

41. This report had been preceded by a number of meetings of an EU expert group on tobacco policy which considered the proposed delegated directive. The minutes of the meeting of the expert group of 9 February 2022 noted that the draft delegated directive concerned not all novel tobacco products but only a particular category of them, being heated tobacco products, and that the definition of heated tobacco products is *"based on the WHO definition of such products"*. It was also stated in the minutes of that meeting that "*the provisions of the draft Delegated Directive do not aim at classifying the heated tobacco products as either smokeless tobacco products or tobacco products for smoking*" noting that "*this decision is entirely up to the Member States on the basis of the characteristics of the HTPs in line with article 19(4) of the TPD.*"

42. The minutes of the expert group meeting of 9 February 2022 also noted that "*Some Member States raised concerns over whether the Commission is empowered to introduce a definition of a new category of tobacco products in a Delegated Act. These Member States claimed that the new definition could only be in* [the TPD]".

43. The Commission adopted the delegated directive on 29 June 2022 notwithstanding these Member States' concerns. This triggered a two-month scrutiny period under article 27(5) TPD (which was extended by a further two months), during which the Council and European Parliament could raise objections. No objections were raised by Council or Parliament. In the context of the discussions in the Council during the scrutiny period, four Member States (Bulgaria, Cyprus, Greece and Italy) submitted a joint declaration formally registering their

objections to the delegated directive, stating *inter alia* that it "*goes beyond the delegated power under* [TPD] *and involves essential elements reserved for the European legislators and, as such, should be submitted to the ordinary legislative review process. In particular, the Commission, by including a definition of 'heated tobacco products' in the Delegated Directive… is according to us exceeding the limits of the delegated powers granted to it by* [the TPD] *(Article 7, paras. 12 and 11, para. 6 respectively).''* These Member States then referenced specifically the Commission's introduction of a definition of "*heated tobacco products*" in the delegated directive and asserted that "*this use of the delegated power by the Commission is problematic and puts the interinstitutional balance to the test creating legal uncertainty and practical difficulties for all parties involved. This act shall not be considered as a regulatory precedent*." (Note from General Secretariat of the Council: Joint Statement of Bulgaria, Cyprus, Greece and Italy, concerning the delegated directive, 12560/22 ADD 1, 23 September 2022).

The Delegated Directive

44. The delegated directive was adopted on 29 June 2022. The delegated directive (in article 1) amended article 7(12) TPD by replacing it with 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*.'

45. The delegated directive (in article 2) amended the heading of article 11 by replacing it with the new heading "*Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products'* i.e. including reference to "heated tobacco products".

46. The first subparagraph of article 11(1) was 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 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).'.*

47. Member States were obliged to publish the "laws, regulations and administrative provisions" necessary to comply with the delegated directive by 23 July 2023 and to apply the provisions of the delegated directive by 23 October 2023. As already noted, Ireland has done so in the 2023 Regulations.

48. It will be noted that the newly substituted article 7(12) TPD contains a definition not previously contained in the TPD, being that of *"heated tobacco product"*. It will further be noted that the definition of heated tobacco product provides that *"depending on its characteristics"*, it may be a *"smokeless tobacco product"* or a *"tobacco product for smoking"*. Those two concepts are already defined in the TPD, as we have seen. This newly defined product, heated tobacco product, is then incorporated into article 11(1) TPD.

49. The explanatory memorandum for the delegated directive (C(22) 4367 final; also dated 29 June 2022, states that:-

> *"Article 7(12) and Article 11(6) of* [the TPD] *do not confer discretion on the Commission but leave it with the technical task of establishing whether there has been a substantial change of circumstance for a particular product category, which is to result in the prohibition on the placing on the market of tobacco products with characterising flavours or containing flavourings and any other components or having certain technical features, extending to that particular product category and in the removal of the Member States' possibility to grant exemptions from certain labelling*

requirements for that product category. The policy choice to prohibit the placing on the market of tobacco products with characterising flavours, with a view to achieving a high level of health protection, for young people in particular, has already been made by the Union Legislature in [the TPD] *itself (see also Recitals 19 and 26 of that Directive). The 'group of experts on tobacco policy' was consulted and provided its advice on this Delegated Directive."*

The test for an Article 267 reference in an alleged invalidity case

50. The CJEU has jurisdiction under Article 267(1) TFEU to "*give preliminary rulings concerning.. (b) the validity …of acts of the institutions…of the Union.*" By contrast, national courts have no jurisdiction to declare the acts of EU institutions invalid: *Case 314/85 Foto-Frost [1987] ECR 4199* ("*Foto-Frost*").

51. Article 267(2) provides that the national court *"may if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling."* Article 267(3) provides that where the question is raised in a court *"against whose decisions there is no judicial remedy under national law,"* that court "shall" bring the matter before the CJEU.

52. As noted, it is well established that national courts have no jurisdiction to determine that acts of EU institutions are invalid (see *Foto-Frost* at para. 20). As explained in *Gaston Schul* (Case C-461/03, judgment of Grand Chamber, 6 December 2005, (ECJ-2008-3-026) "*Gaston Schul*")) the possibility of a national court ruling on the invalidity of a Union act is incompatible with the necessary coherence of the system of judicial protection instituted by the (then) EC treaty (at para 22):-

"It is important to note in that regard that references for a preliminary ruling on validity constitute, on the same basis as acts for annulment, a means of reviewing the legality of Community Acts. By [*inter alia* Articles 263 and 267] *the Treaty established a complete system of legal remedies and procedures designed to ensure review of the legality of acts of the institutions and has entrusted such review to the Community Courts."*

53. As further explained in *Gaston Schul*, (at para. 21) the main purpose of the jurisdiction conferred on the CJEU by article 267 is to ensure that EU law is applied uniformly by national courts:-

> *"That requirement of uniformity is particularly vital where the validity of a Community Act is in question. Differences between courts of the Member States as to the validity of Community Acts would be liable to jeopardise the essential unity of the Community legal order and undermine the fundamental requirement of legal certainty."*

54. The parties are agreed that the test governing the question of when a national court is under an obligation to make a reference to the CJEU under article 267 for a preliminary ruling on the validity of an EU act is that set out in Case C-344/04 *International Air Transport Association v. Department for Transport* (judgment of the Court (Grand Chamber), 10 January 2006) (*"IATA"*), where is was held (at para. 30) that where a national court considers that one or more arguments for the invalidity of a Community/Union act are *"well founded"*, it is incumbent upon the national court to stay the national proceedings and to make a reference to the CJEU for a preliminary ruling on that act's validity.

55. It appears that the CJEU has not elaborated in terms on the concept of *"well founded"*. However, it is clear from the context of the judgment in *IATA* that the term *"well founded"* in relation to an argument relates to the stateability or substantiality of the argument; as the Court makes clear at para. 29 of *IATA*, if the arguments put forward in support of invalidity are *"unfounded"*, the court may reject them and conclude that the EU act in question is completely valid.

56. Counsel for the State submitted that the test was more than a mere arguability test or a test of the relevant arguments as to validity not being unstateable (to deploy concepts familiar to domestic law in the Irish courts); rather, there must be sufficient substance to the argument before it can be regarded as "well founded". In that regard, it was pointed out that the CJEU, at para. 27 of its judgment on the TPD validity challenge, noted that the High Court of England and Wales in that case regarded as *"reasonably arguable"* certain arguments which were the subject of an Article 267 reference and referred questions on that basis.

57. In my view, assistance on this issue can be found in the CJEU's judgment in *Gaston Schul*. There, the CJEU considered whether the third paragraph of article 234 EC (now article 267

TFEU) (i.e. "*Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court of Justice"*) required a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law to seek a ruling from the Court of Justice on a question relating to the validity of the provisions of a regulation even where the Court has already declared invalid analogous provisions of another comparable regulation. In its analysis of the issue, the Court of Justice noted (at para 16):

> "*With regard to questions of interpretation, it is clear from the judgment in Case 283/81 Cilfit and Others [1982] ECR 3415, paragraph 21, that a court or tribunal against whose decisions there is no judicial remedy under national law is required, where a question of Community law is raised before it, to comply with its obligation to bring the matter before the Court of Justice, unless it has established that the question raised is irrelevant or that the Community provision in question has already been interpreted by the Court or that the correct application of Community law is so obvious as to leave no scope for any reasonable doubt*".

58. Counsel for the notice parties submitted that this provided an appropriate guide to a national court such as this court in applying article 267 to the context of a situation where the validity of an act of an EU institution was in issue (as opposed to the interpretation of such an act) given the common policy underpinning in article 267 for both types of references; one would certainly not expect the threshold for triggering the obligation to refer questions of validity to be any less than that for referring questions of interpretation. I agree. In my view, the national court will have an obligation to refer a question concerning the validity of an act of an EU institution (assuming the question is relevant and has not previously been the subject of a validity ruling) unless the validity of the EU act "is so obvious as to leave no scope for any reasonable doubt". This seems to me to be consistent with the requirement in *IATA* that an argument justifying a reference on a validity issue be "well-founded" in the sense that it is not unfounded.

59. I will accordingly proceed to consider whether the applicants (and notice parties) have identified well-founded arguments as to the invalidity of the delegated directive applying the foregoing conception of "well-founded" i.e. do the arguments raise reasonable doubt as to the validity of the EU act in issue? In short, are they reasonable arguments?

Invalidity case – alleged breaches of Article 290

Overview of article 290

60. The first set of invalidity arguments advanced by the applicants (and supported by the notice parties) are those relating to alleged breaches of article 290 TFEU ("article 290") by the Commission in implementing the delegated directive; in particular, arguments that the Commission exceeded its delegated powers under the TPD by virtue of the amendments to the TPD purported to be effected by the delegated directive.

61. Article 290(1) TFEU provides as follows:

> *"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.*
>
> *The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power."*

62. For ease, I will refer to the two subparagraphs of article 290(1) as "the first subparagraph" and "the second subparagraph".

63. The applicants do not seek to impugn the validity as a matter of EU law of article 7(12) and article 11(6) of the TPD insofar as those provisions empower the Commission to make delegated legislation. Indeed, they could not do so in light of the judgment of the CJEU in respect of the TPD validity challenge. Rather, the applicants focus their fire on an alleged excess of exercise by the Commission of its legitimately conferred delegated powers.

64. The question of the proper interpretation and application of article 290 has been considered in a number of CJEU decisions including *Parliament v Council* (Case C-355/10, EU:C:2012:516)

("*Parliament v Council")*; *Parliament v. Commission* (Case C-286/14, EU:C:2014:170); *Dyson v. Commission* (Case C-44/16, EU:C:2017:357) ("*Dyson"*); and *Czech Republic v European Commission* (Case C-696/15 EU:C:2017:595) ("*Czech Republic*").

65. The CJEU has made clear that the "*essential elements"* of basic or primary legislation within the meaning of article 290(1) are those which *"...require political choices falling within the responsibilities of the EU legislature*": *Parliament v Council* at para. 65. In *Czech Republic,* the Court, at para. 78, elaborated on the concept of "political choices" in this context as follows:

> *'An element is essential within the meaning of the second sentence of the second subparagraph of Article 290(1) TFEU in particular if, in order to be adopted, it requires political choices falling within the responsibilities of the EU legislature, in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments, or if it means that the fundamental rights of the persons concerned may be interfered with to such an extent that the involvement of the EU legislature is required (see, to that effect, judgment of 5 September 2012, Parliament v Council C-355/10, EU:C:2012:516, paragraphs 65, 76 and 7).*

66. Furthermore, ascertaining the elements of a matter which are "*essential"* must be based *"on objective factors amenable to judicial review, and requires account to be taken of the characteristics and particular features of the field concerned*": *Czech Republic* at para. 77 (see also *Dyson* at para. 62).

67. I will turn now to assess the arguments as to the alleged invalidity of the delegated directive by reference to the foregoing principles.

The case for invalidity of the delegated directive

68. The applicants contend that when articles 7(12) and 11(6) impose an obligation on the Commission to withdraw exceptions for "*a particular product category*" or "*particular product categories*", the product categories in question are those specifically listed in article 2(14)(a) TPD (i.e. the various categories of tobacco product in existence at the time of enactment of the TPD and defined in the TPD) and therefore do not empower the Commission to withdraw exemption for a product which a "*novel tobacco product*" as defined in that article.

They say that this reading is supported by the CJEU's decision in Case C-220/17 *Planta-Tabak Manufaktur* (ECLI:EU:C:2019:76) ("*Planta-Tabak*") (at paras. 61-67), a case which concerned the proper interpretation of the phrase "product category" in article 7(14) TPD.

69. More fundamentally, the applicants and notice parties submit that the Commission's delegated powers in articles 7(12) and 11(6) cannot be used to define and then regulate (to the point of outright prohibition) novel tobacco products that the EU legislature has never specifically considered and made political choices in respect of. They contend that both limbs of the second subparagraph of article 290(1) have been breached by the delegated directive. They say that introducing a new tobacco product category (that of *"heated tobacco product"*) by inserting a definition of that new category by amendment of article 7(12) and then purporting to regulate that new category by withdrawing the benefit of the exemptions for that category in article 7(12) and article 11(6) involves legislating for a political or policy choice which is an essential element of the TPD is reserved to the legislative act and cannot be the subject of a valid exercise of delegated power i.e. that there has been a violation of the second sentence of the second subparagraph of article 290(1) which provides that "*the essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power*." They also contend that the Commission in enacting the delegated directive has breached the first limb of the second subparagraph of article 290(1) (i.e. that "*the objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative act*") in that no power to define a new tobacco product category, and thereafter regulate it by withdrawal of an exemption, was explicitly conferred by the TPD.

70. The applicants and notice parties contend that the overall structure of the TPD reflects that the EU legislature has set up a system in which tobacco products that were known at the time the TPD was enacted could be subject to certain further obligations by delegated acts of the Commission, whereas new or little-known products should be monitored so as to allow the legislature to adopt new restrictions in the future when the nature and effects of such products have been established and appropriate legislative responses decided upon at primary level. They say that this is reflected in the terms of the TPD with the creation of specifically defined categories of tobacco products in article 2 and the regulation of these categories depending on which specifically defined product is in issue, such that, for example, article 3 deals with cigarettes; article 6 deals with cigarettes and roll you own tobacco; article 7 with cigarettes and roll your own tobacco with a characterising flavour; article 20 with e-cigarettes, and so on.

They contend that the policy of the TPD as evident in article 19 is that, in contrast, novel tobacco products are to be monitored with a view to identifying specific responses to such developments by new laws as necessary. In this regard, the applicants rely on the 2012 explanatory memorandum for the TPD which they say makes clear that the concept of a "particular product category" as referenced in article 7(12) is synonymous with an established product category, i.e. established at the time enactment of the TPD and not, in contradistinction, a novel tobacco product. They also rely on article 28(2) which provides that the Commission, in its review report, must pay "special attention" to "market developments concerning novel tobacco products" (article 28(2)(b)) and, separately, "developments which constitute substantial change of circumstances" (article 28(2)(c)) thereby, they say, underscoring that the substantial change of circumstances analysis applies to pre-existing and not novel tobacco products under the TPD.

71. The applicants rely on the analysis and conclusion in the 2021 Commission review report (set out earlier at paragraphs 38 and 39 of this judgment) which they say signalled an acceptance by the Commission that novel tobacco products such as heated tobacco products presented particular regulatory challenges which, the applicants say, could only be addressed by primary legislation.

72. By way of illustration of the manner in which the Commission has exceeded its delegated powers, and impermissibly strayed into seeking to legislate for essential elements of the TPD, the applicants point out that the new category of heated tobacco products as defined in the delegated directive comprises both tobacco products that are "*smokeless*" as well as tobacco products that are "*for smoking*". The TPD, however, clearly distinguishes between smokeless tobacco products and tobacco products for smoking, and sets very different and more onerous labelling and packaging rules for the latter. They argue that as the TPD explicitly provides in article 19(4) for novel tobacco products to fall within one category or the other; such a product cannot fall into both. They say that this fortifies the essentially legislative character of what the Commission purported to do in the delegated directive.

73. Finally, the applicants also say the fact that there are well-founded concerns as to the invalidity of the delegated directive is borne out by that the fact that, as noted earlier in this judgment, several Member States expressed concerns regarding the delegated directive on the grounds

that the Commission in introducing the delegated directive was legislating in excess of its delegated powers.

State's arguments against invalidity case

74. The State submits that the applicants' case fails to reflect the fact that the TPD seeks to cast a wide and dynamic regulatory net in keeping with the objectives for which the TPD was introduced, being to harmonise the common market in tobacco products, to take as a base a high level of protection for health, and to be in a position to react to market developments including the introduction of novel tobacco products. The TPD, it submits, is clear in covering all *"tobacco products*" within the wide definition of that concept in article 2 TPD which inevitably includes both tobacco products of the "old fashioned" variety, which were in existence in April 2014, at the time of the enactment of the TPD, and novel tobacco products within the wide definition of same found in article 2(14) of the TPD i.e. tobacco products which have come into being since April 2014, such as HTPs. The State submits that there is no definition of *"other product categories"* in article 7(12) (or "*particular product categories"* in article 11(6)) and those phrases must accordingly be given their ordinary meaning, adopting a teleological interpretation of the TPD, i.e. that they include any tobacco product category, including HTPs, which is not cigarettes or roll your own tobacco and which comes within the broad umbrella definition of *"tobacco product"*. The State submits that, in essence, the applicants' case depends on a carve out from those articles of novel tobacco products, when such a carve out is found neither in the language nor purpose of those provisions.

75. The State contends that while the applicants and notice parties accept that their HTPs are within the prohibitions in article 7(1) and article 11(1) and the exemptions from those prohibitions in article 7(12) and article 11(6), the applicants/notice parties then artificially and in a manner inconsistent with the objectives and wide regulatory net of the TPD, seek not to be subject to those parts of articles 7(12) and 11(6) which mandate the Commission to disapply the exemptions once the substantial change of circumstances criteria are met. The applicants' case, they submit, would effectively give *carte blanche* to the unregulated introduction of flavoured novel tobacco products, such as flavoured HTPs, in a manner inconsistent with the express regulatory objectives of the TPD. In this regard, they emphasise that article 19(4) makes clear

that the provisions of the TPD apply to novel tobacco products which must mean that articles 7(12) and 11(6) apply to HTPs.

76. The State submits that the applicants' case poses the wrong question (i.e. the question of where the power to create new categories of products comes from within the terms of the TPD); it submits that the correct question, rather, is whether the withdrawal from the exemption from prohibition of tobacco products with characteristic flavouring pursuant to articles 7(12) and 11(6) is a technical task which occurs once certain objective criteria are met, being the criteria amounting to substantial change of circumstance within article 2(28) of the TPD. The State says that the policy issues and political questions on these matters are all resolved within the terms of the TPD. The essential elements - of a level playing field, a high level of protection for health, in particular that of young people, and the principle that the TPD's regulatory measures apply to all tobacco products, whether existing or novel – are all enshrined in the TPD itself and the impugned provisions simply set out the scope of the technical task which the Commission properly embarked upon in respect of HTPs in furtherance of the delegated powers given to it to implement the policy matters already decided upon in the provisions of the TPD.

77. The State submits that the explanatory memorandum for the delegated directive correctly made clear that the policy choices to prohibit the placing on the market of tobacco products with characterising flavours had already been made by the EU legislature in the TPD itself (as supported by recitals 19 and 26). The State submits that the delegated power clearly extends to defining a new tobacco product category for the purposes of disapplying the exemption from prohibition contained in article 7(12) (and the power of Member States to so de-exempt in article 11(6)) as part of the policy of fulfilling the technical task of determining whether any given tobacco product is the subject of a substantial change of circumstance. The State contends that the TPD itself respects the content of, and proper limits to, article 290 as borne out by recitals 51 and 52 (set out at paragraphs 31 and 32 of this judgment) and the provisions of articles 27 (dealing with exercise by the Commission of its delegated powers) and 28 (dealing with the Commission's review and reporting obligations). The policy on full regulation by prohibition of flavoured tobacco products is borne out by e.g. recital 15 (which, *inter alia*, notes the FCTC guidelines which call for the removal of "ingredients that increase palatability"). All that is involved in articles 7(12) and 11(6) is the technical task of determining whether a substantial change of circumstance has occurred in relation to a particular product category.

HTPs are unquestionably a tobacco product category. If such a substantial change of circumstance has occurred, the Commission has no discretion and is mandated to disapply the relevant exemption.

78. As regards the other arguments raised by the applicants and notice parties, the State made the following points.

79. The State contended that the contents of the 2021 Commission report made clear that the Commission believed that there was a power to exempt (and, therefore, de-exempt) novel tobacco products under article 7(12) but was equally expressing the view that there may need to be a more radical overhaul in respect of certain novel tobacco products; there is no inconsistency between those positions. The relevant view of the Commission in its 2021 review report, for present purposes, was that the Commission (correctly) regarded novel tobacco products as being within the de-exemption power with in article 7(12) (see paragraph 37 of this judgment). Insofar as the Commission's 2021 review identified certain issues of categorisation or characterisation in respect of some novel tobacco products, including HTPs, the State says that the delegated directive seeks to sensibly cover the possibility that any given HTP may be either a smokeless tobacco product or a tobacco product for smoking within the meaning of the TPD; this approach does not overstep the Commission's delegated powers.

80. The State contends that there is nothing inconsistent in article 28(2) as between the obligation on the Commission to monitor market developments in respect of novel tobacco products and to also market developments constituting a substantial change of circumstance. There was no necessary inconsistency between such type of market developments.

81. The State submitted that the *Planta Tabak* case was confined to the specific question of the proper interpretation of *"other product category"* in article 7(14) of the TPD and did not provide support for the quite different case now sought to be made by the applicants and notice parties.

82. In summary, the State's position was that there was no well-founded argument as to any breach by the Commission of article 290 in introducing the delegated directive as the delegated directive was entirely consistent with the aims of the TPD, which proceeded from the premise that flavoured tobacco products were prohibited, subject to certain exemptions which could be withdrawn, which provisions applied to all tobacco products. The delegated directive was

properly promulgated pursuant to the express powers conferred on the Commission by articles 7(12) and 11(6); the objectives, content and scope of the delegated directive were expressly delimited by the relevant provision of the TPD; no essential elements were being improperly legislated for by the Commission. There was no basis in the language or rationale of the TPD for the contention that the exemptions (and their withdrawal) would not apply to novel tobacco products, such as HTPs. There was simply no substance to the contention that the undefined phrase *"particular product categories"* in article 7(12) meant only those particular product categories which were in existence and which were defined in the TPD at the time of its enactment. Such an interpretation would fundamentally subvert the objectives, purpose and plain language of the TPD.

Conclusion on whether delegated power/article 290 invalidity arguments are well-founded

83. In my view, there are well-founded arguments as to the invalidity of the delegated directive on the following grounds:

(i) that in defining a new category of tobacco product, being HTPs, and deciding that such category should be denied the benefit of the exemptions in articles 7(12) and 11(6) (thereby leading to the total prohibition on flavoured heated tobacco products), the Commission was invalidly making a political choice to the effect that a category of tobacco product which was new on the market, which had not been in existence at the time of the enactment of the TPD in 2014 and which had not been the subject of separate policy and health assessments by the EU legislature should nonetheless be prohibited on the basis of the volume of sales (sales volume being the key criterion in article 2(28) when assessing whether there has been a substantial change of circumstance). It is at least arguable that this involved a political choice which was only open to the EU legislature and not to the Commission.

(ii) that the structure of the TPD is such that the EU legislature would keep novel tobacco products under review in light of scientific and technical developments and that questions of outright prohibition, particularly where products might not be readily categorizable into smokeless tobacco products or tobacco products for smoking, and where such products may not have the same level of tobacco content

as existing products, would be addressed by primary legislation once policy choices were made by the legislature as to how best to regulate such new products. To define a new category of product, which straddles both smokeless and smoking tobacco products, for the purposes of immediately prohibiting a flavoured version of such a new product arguably breaches the two limbs of the second subparagraph of article 290(1) by purporting to legislate for an essential element and where the scope, content and objective of such a choice was not explicitly defined in the TPD.

(iii) The validity arguments presuppose that the Commission would have the delegated power to de-exempt all flavoured novel tobacco products from prohibition if such products met the sales volume conditions of article 28(2), irrespective of the tobacco content or health impact of such products relative to existing products. For example, if a flavoured novel tobacco product contained, say, 1% tobacco (i.e. considerably less than existing tobacco products in the market) and the sales volume criteria in article 28 for that new product were met (including the necessary condition of achieving over 2.5% of the overall market by volume sales, assuming such sales volume is validly assessed by unit and not by tobacco weight), then that product would be prohibited notwithstanding that the health impact of such product may be very different to that of existing products with much higher tobacco content. This would arguably involve the Commission in the making of political choices which it is not empowered to do.

84. These arguments seem to me to be reasonable arguments. I cannot hold that the arguments are so devoid of merit as to leave no scope for any reasonable doubt that the delegated directive is completely valid.

85. As I have found that there are well-founded arguments that the Commission in enacting the delegated directive has impermissibly encroached on the EU legislature's exclusive sphere of legislating contrary to article 290, I propose to refer the question of the validity of the delegated directive to the CJEU pursuant to article 267 TFEU.

Alleged fundamental flaw in determination of substantial change of circumstances

86. The applicants also advanced a further ground of alleged invalidity of the delegated directive on the basis that the manner in which the Commission approached the question of substantial

change of circumstances in its article 28(2) assessment exceeded the Commission's delegated powers under the relevant provisions of the TPD. In order to put this case in context, it is necessary to briefly refer to a number of discrete provisions of the TPD.

87. Article 5(1) TPD provides that Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities various specified information by brand name and type, including information as to the weight by ingredient in each tobacco product. Article 5(6) provides *inter alia* that Member States shall 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"*. Accordingly, the TPD expressly provides for the entitlement of Member States to require manufacturers to report in sticks as opposed to kilograms.

88. Article 5(5) provides that the Commission shall by means of implementing acts lay down the format of making available of such information. Such an implementing decision was promulgated by the Commission's "*implementing decision establishing a format for the submission and making available of information on tobacco products*" of 25 November 2015 ((EU) 2015/2186) pursuant to article 5(5) of the TPD ("the implementing decision"). This sets out (in Article 2) a format for data submission on, *inter alia*, sales volumes in accordance with a format provided for in an annex to the implementing decision. The format provides for the provision of information by product type, including product weight and *"product sales volume"*. In relation to *"product sales volume"*, the annex provides that the information to be provided is "*information on annual sales volume of the product per Member State to be reported annually in product units or in Kg loose tobacco*."

89. The definition of *'substantial change of circumstances'* is found in article 28(2) (as set out at paragraph 22 above). For present purposes, it is only necessary to refer to the last limb of the relevant test which provides that "*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 Union level'.*

90. As noted earlier, (see paragraph 40 above), on 15 June 2022, the Commission published a report pursuant to article 28(2) on the establishment of a substantial change of circumstances for heated tobacco products (**'**the substantial change of circumstances report'**)**.

91. The Commission's substantial change of circumstances report states that the analysis presented in the report is based on data transmitted in accordance with article 5(6) of the TPD *via* the EU Common Entry Gate, data collected from the EU Tobacco Traceability System established under Article 15 of the TPD and Euro Monitor International Passport Tobacco 2021 data. The relevant analysis is conducted by reference to unit/sticks and not weight.

92. The substantial change of circumstances report established in respect of HTPs that *inter alia*:

    a. the sales volumes of HTPs at retail level increased by a percentage higher than 10 per cent in more than five Member States between the defined period of 2018–2020: and

    b. the sales volumes of HTPs at retail level corresponded to 3.3 per cent of the total sales volume of all tobacco products at Union level for the year 2020.

93. The sales volume data in the Commission report was on a "per stick" or per unit basis with appropriate adjustments made for products not sold in sticks (such as roll your own tobacco).

94. There was no issue taken by the applicants with the Commission's application of the first limb of article 2(28). Their case focused rather on the last limb, being the necessary condition in relation to the calculation of the 2.5% market share. The applicants contend that the Commission devised and relied on a flawed methodology in its examination of whether the last limb of article 2(28) had been satisfied. In doing so, that say that the Commission exceeded the scope of the "*technical task*" conferred upon it under articles 7(12) and 11(6) such as to invalidate the delegated directive.

95. There was no evidence advanced by the applicants of any error in how the Commission applied the sales volume data on a per stick basis; rather issue was taken with relying on the per stick data *per se*.

96. The applicants contend that the Commission improperly relied on volume of cigarettes and other tobacco products, including heated tobacco products, on a "per stick" basis when it should have relied on a "per weight" basis in circumstances where heated tobacco products have some 50% of the weight of tobacco which ordinary cigarettes have and where the 'per weight' information was available the Commission such as to enable a more reliable "like for like"

sales volume analysis. The applicants say that in adopting such a fundamentally flawed methodology the Commission exceeded the scope of the technical task conferred on it by articles 7(12) and 11(6).

97. The applicants contend that the amount of tobacco in each of the various product categories, including heated tobacco products, could have been the only correct criterion for the Commission's calculations given the TPD's focus on regulating the health effects of tobacco. The Commission's decision to use a stick-based calculation without taking into consideration the differences in the amount of tobacco in the sticks of different products, is flawed and unreliable, say the applicants. The applicants point out that tobacco product manufacturers and distributors are obliged by virtue of the implementing decision to provide data on tobacco weight per product, meaning that the Commission had the necessary data to properly conduct a fair and valid assessment of market share by reference to the more appropriate metric of tobacco weight. If market share of heated tobacco products had been measured by weight and not on a stick basis, the applicants maintain that the 2.5% threshold established by the last limb in article 2(28) would not have been breached. Accordingly, it contends that the Commission exceeded its delegated powers by devising a fundamentally flawed methodology that led to a fundamentally flawed outcome to the substantial change in circumstance analysis with the improper result that flavoured HTPs were prohibited by the delegated directive when they should not have been.

98. The State, for its part, submitted that the TPD made clear in article 5(6) that the volume of sales reported could be either on a weight or stick basis and there was, therefore, nothing improper in the approach taken by the Commission. The definition of the term *'substantial change of circumstances'* itself does not specify the method by which sales volumes are to be assessed. The State says that the use of a stick basis to measure sales volume is expressly envisaged and permitted by the terms of the TPD, including by article 5(6). The State says that the implementing decision mandates the provision of data *inter alia* by stick per product. It submitted that data was provided to the Commission in accordance with the requirements of article 5(6) and the implementing decision under article 5(5). Accordingly it contends that there is simply no well-founded argument that the Commission has engaged in an invalid act; the Commission conducted the analysis in accordance with data validly provided pursuant to the implementing decision and pursuant to the provisions of the TPD itself. Accordingly, there is no arguable basis for any manifest error or excess of jurisdiction in that regard.

99. For completeness, I should say the State also pointed to the fact that BAT plc itself reports its sales of cigarette products including heated tobacco products by unit or stick and not by weight: this is evident in BAT plc's half year report to 30 June 2022 which was before the court. In a section of the report headed *"Non-Financial KPIs"* under the heading *"Volume"*, BAT states that volume is defined as the number of units sold and that volume is used by management and investors to assess the relative performance of the group and its brand within categories. I do not see that this is relevant to the question of the validity of the methodology applied to the substantial change of circumstance here and whether such methodology exceeded the Commission's delegated powers under the TPD.

100. In my view, the applicants have established a well-founded argument as to the validity of the Commission's fulfilment of the task of determining whether there had been a substantial change of circumstances pursuant to article 2(28), on the basis that the Commission's quantitative sales volume analysis did not compare like with like when such a like for like analysis appears to have been legally and factually open to the Commission. One of the TPD's core objectives is protection of health given the harmful effects of tobacco. Accordingly, tobacco content of tobacco products is a key concern driving the TPD's regulatory measures. On the face of it, no attempt was made in the Commission's substantial change of circumstance methodology to equalise the metrics as between HTPs and cigarettes (and other tobacco products) as regards tobacco content to ensure that like was compared with like when assessing whether the level of penetration of HTPs in the market was such as to warrant prohibition of flavoured HTPs in furtherance of the health protection objective. An approach which focused on overall tobacco content of products and assessed sales volume on that basis would have arguably been more consistent with the objectives of the TPD in so far as the tobacco component of products is the material component for the purposes of engaging with the objective of protecting health. There is a reasonable argument that the fact that the Commission may *prima facie* have had the power to approach the analysis by reference to sales volume on a per stick or unit basis did not relieve the Commission of the obligation to ensure that the underlying objectives of the TPD in terms of health protection were best met by another option open to the Commission i.e. that of assessing comparative sales volumes on a tobacco content basis. Given that the relatively low threshold for establishing a well-founded argument on this issue has been made out, I propose to refer a question to the CJEU on this issue.

Alleged failure to state reasons contrary to Article 296 TFEU and infringement of the principle of good administration

101. Article 296 TFEU provides, *inter alia*, that legal acts of the EU shall state the reasons on which they are based.

102. The applicants in their submissions asserted that the obligation to provide a statement of reasons for a legal act under article 296 TFEU is "*an essential procedural requirement*" and "*must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure in such a way as to enable the persons concerned to ascertain the reasons for it and to enable the competent European Union judicature to exercise its power of review*," as stated by the CJEU in Case C-280/08 *Deutsche Telekom v Commission* ECLI:EU:C:2010:603 at para. 76. They submitted that the delegated directive does not satisfy these requirements as the Commission did not adequately explain how the conditions for its delegated powers are fulfilled and did not disclose the underlying documents used in its calculations, shielding the measure from any possible scrutiny. Given these failings and the administrative irregularity of the Commission's conduct, the applicants contend that the Commission also infringed the principle of good administration.

103. The applicants articulated their case on the basis in their Statement of Grounds in terms that the Commission has not adequately explained how the conditions for the exercise of its delegated powers were fulfilled including that the Commission did not explain why it assessed market share on a stick basis as opposed to a tobacco weight basis and that the Commission did not provide public access to the underlying data on which the calculations as to substantial change of circumstances were based.

104. It was does not seem to me that a well-founded argument has been raised on this ground. If the applicants succeed on the flawed methodology ground, the reasons argument falls away. Conversely, if the applicant fails on the flawed methodology ground, it is manifest that the Commission in its report on substantial change of circumstance has set out the reasoning for its conclusion that a substantial change of circumstances had occurred in a way that would enable any interested party to ascertain the reasons for it. No authority was advanced for the

proposition that the Commission had some legal obligation to disclose to the public all of the underlying data it relied upon. No evidence was led by the applicants to suggest that the Commission had relied on data which was not contemplated by the terms of the implementing decision or the terms of article 5(6) or article 2(28) itself. Accordingly, I do not propose to refer any question to the CJEU on this issue.

Conclusions on question of reference

105. In light of the provisions of article 267 TFEU and the case law thereunder (as discussed earlier), given that I have identified well founded arguments as to the validity of the delegated directive, it is necessary to refer questions as to the validity of the delegated directive to the CJEU pursuant to article 267.

106. In its judgment on the TPD validity challenge case, the CJEU stated (at para. 48) that it was important that the national court should set out, on a reference, *"the precise reasons which led it to question the validity of certain provisions of EU law and set out the grounds of invalidity which, consequently, appear to be capable of being upheld"*. This is reflected in para. 7 of the "*recommendations of the CJEU to national courts and tribunals in relation to the initiation of preliminary ruling proceedings*" (2019/C 380/01) which states that when the national court has doubts about the validity of an act of an EU institution, the national court must refer the matter to the [CJEU] "*stating the reasons why it has such doubts*". I have sought in this judgment to identify the reasons which lead me to question the validity of the delegated directive and the grounds of invalidity which appear to be capable of being upheld.

107. I will turn next (and finally) to the question of the timing of the reference to the CJEU.

Should the Court refer the questions now?

108. The applicants (and other BAT group entities) and members of the PMI group lodged annulment proceedings with the General Court of the CJEU on 16 November 2020, pursuant to article 263 TFEU. In these annulment proceedings, the applicants maintain that the delegated directive is invalid, advancing substantially the same grounds of invalidity as are relied on in these proceedings. The Commission has lodged an admissibility objection in the annulment proceedings, which is currently being considered by the CJEU. The State submits that it would be appropriate to defer the timing of any reference to the CJEU under article 267 until after

determination of the question of admissibility in the annulment proceedings as, if those proceedings are deemed admissible, it may be unnecessary to refer any questions at all as the CJEU will then in the annulment proceedings determine the very issues which are the subject of the proposed reference in this case. The applicants, for their part, say that there is no good reason not to make the reference immediately and that they still stand to be prejudiced in the event that there is any delay, particularly given that there is a risk that the CJEU will hold the annulment proceedings inadmissible.

109. There is clearly no bar to this court making a reference just because the applicants have also instituted annulment proceedings before the General Court. In Case C-72/15 *PJSC Rosneft Oil Company v. HM Treasury & Ors.*, (ECLI:EU:C:2017:236), the CJEU stated (at para. 70) that

> *"Neither the EU Treaty nor the FEU Treaty indicates that an action for annulment brought before the General Court… constitutes the sole means for reviewing the legality of decisions providing for restrictive measures against natural or legal persons, to the exclusion, in particular, of a reference for a preliminary ruling on validity."*

110. In *Inuit Tapiriit C—583/11P* (ECLI:EU:C:2013:625), the Court stated (at para. 95) that "*references for preliminary rulings which seek to ascertain the validity of a measure constitute, like actions for annulment, means for reviewing the legality of European Union acts*."

111. As made clear by the CJEU in *A, B, C and D v. Minister van Buitenlandse Zaken* (Case C-158/14, 14 March 2017) at para. 67:-

> *"It is only in circumstances where the action for annulment would unquestionably have been admissible that the court has held that a person may not plead the invalidity of an Act of the European Union before a National Court"*.

112. I am satisfied that this is not the situation in the present case. The Commission has contested the admissibility of the annulment proceedings and a decision is awaited from the CJEU on that admissibility objection. Accordingly, this is not a situation where the action for annulment is *"unquestionably"* admissible before the CJEU.

113. The CJEU has an express procedural mechanism to manage situations in which "*the Court of Justice and the General Court are validly seised of cases in which the object is identical or similar*." (Lenaerts *et al*., *EU Procedural Law* para. 2.55.) Article 54 of the Statute of the Court of Justice confers a wide discretion on the Court to manage related proceedings as it sees fit:

> *"Where the Court of Justice and the General Court are seised of cases in which the same relief is sought, the same issue of interpretation is raised or the validity of the same act is called in question, the General Court may, after hearing the parties, stay the proceedings before it until such time as the Court of Justice has delivered judgment or, where the action is one brought pursuant to Article 263 of the Treaty on the Functioning of the European Union, may decline jurisdiction so as to allow the Court of Justice to rule on such actions. In the same circumstances, the Court of Justice may also decide to stay the proceedings before it; in that event, the proceedings before the General Court shall continue."*

114. The Rules of Procedure of the Court of Justice in turn provide that "*... proceedings may be stayed: (a) in the circumstances specified in the third paragraph of Article 54 of the Statute* [of the CJEU]*, by order of the Court, made after hearing the Advocate General.*"

115. I was referred to a number of authorities on the question of the factors which the national court can take into account when deciding on the timing of a reference to CJEU pursuant to article 267, in particular the cases of *JTI Ireland Limited v. Minister for Health and Ors.* [2015] IEHC 481 ('*JTI*') and *Friends of the Earth v Minister for Communications* [2020] IEHC 383 ("*Friends of the Earth")*. Those factors include whether a reference has been made from another Member State court on an identical or similar issue or whether similar proceedings are pending. It was fairly accepted by counsel for the State that those cases were distinguishable from the case before me. *JTI* involved a scenario where the very questions the subject of the reference application in the proceedings in this jurisdiction had some months previously been the subject of a reference by the English courts to the CJEU, and where a decision from the CJEU on that reference was reasonably imminent, a scenario which does not apply here. *Friends of the Earth* involved an application to the High Court for a reference in circumstances where that court was not seised of any underlying dispute in respect of which it had jurisdiction

to deliver judgment; in both circumstances, the view was taken that a preliminary reference pursuant to article 267 was not "necessary" to enable the High Court to give judgment.

116. In my view, it is appropriate for this court to refer questions as to the validity of the delegated directive to the CJEU at this juncture. An answer to the questions to be referred is necessary in order to determine the core issue in these proceedings of the validity of the 2023 Regulations which are shortly to come into force. The State will suffer no prejudice in the event that I refer the questions now as opposed to on a later date. In contrast, the applicants and notice parties stand to be prejudiced in circumstances where they will be prohibited from October next from selling flavoured HTPs notwithstanding that there are well-founded arguments that the delegated directive (and, by extension, the 2023 Regulations) are invalid as a matter of EU law.

117. Accordingly, in my view, it is necessary and appropriate to refer questions as to the validity of the delegated directive to the CJEU at this point. It will then be a matter for that court to determine how to manage its docket as between the annulment proceedings pursuant to article 263 and the article 267 reference I propose to make.

Conclusion

118. In conclusion, for the reasons set out in this judgment, in my view there are well-founded arguments as to the validity of the delegated directive in two respects, and I will proceed to refer questions on those issues of invalidity to the CJEU pursuant to article 267. I will discuss with counsel for the parties the appropriate wording of the questions to be referred.