In the High Court of Justice
Queen's Bench Division
Administrative Court

CO/3471/2016

In the matter of an application for judicial review

THE QUEEN

on the application of

SWEDISH MATCH AB

Claimant

-v-

SECRETARY OF STATE FOR HEALTH

Defendant

NEW NICOTINE ALLIANCE

Intervener

UPON the Claimant's application for a reference to the European Court of Justice pursuant to CPR Pt 68;

AND UPON consideration of the documents lodged by the parties pursuant to the order of 27 January 2017;

Order by the Honourable Mrs Justice Lang DBE

1. The questions set out in the attached schedule are referred to the European Court of Justice for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union.
2. The claim for judicial review be stayed pending final determination of the giving of a preliminary ruling by the European Court of Justice.
3. Costs reserved.

Signed: Rowena Lang

The date of service of this order is calculated from the date in the section below

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Sent / Handed to the Claimant, Defendant and any Interested Party / the Claimant's, Defendant's, and any Interested Party's solicitors on (date):

Solicitors:
Ref No: jmh/jd/elp/801384.0001

09 MAR 2017

CO/3471/2016

IN THE HIGH COURT OF JUSTICE
QUEENS BENCH DIVISION
ADMINISTRATIVE COURT

BETWEEN:

THE QUEEN
On the application of
SWEDISH MATCH

Claimant

And

THE SECRETARY OF STATE FOR HEALTH

Defendant

And

THE NEW NICOTINE ALLIANCE

Intervener

SCHEDULE

1. By the present reference, made pursuant to Article 267 of the Treaty on the Functioning of the European Union, the High Court of Justice (Queen's Bench Division) Administrative Court requests a preliminary ruling regarding to the validity of Articles 1(c) and 17 of Directive 2014/40/EU of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (the "**Tobacco Products Directive 2014**" or "**2014 TPD**").

2. In accordance with Article 94 of the Procedure Rules of the Court of Justice, an account of the facts giving rise to the reference is set out below.

Proceedings giving rise to the reference

3. The reference arises from a judicial review challenge brought by Swedish Match to Regulation 17 of the Tobacco and Related Products Regulations 2016 (the "**TRP Regulations**"), which provides that "*no person may produce or supply tobacco for oral use*". The TRP Regulations entered into force in the United Kingdom on 20 May 2016.

4. Regulation 17 of the TRP Regulations ("**Regulation 17**") gives effect to Article 1(c) and Article 17 of 2014 TPD, which require the Member States (other than Sweden) to prohibit the marketing of an oral tobacco product known as '*snus*'. Swedish Match, a company that produces snus, issued a challenge to Regulation 17 on 30 June 2016.

Permission to bring the claim was granted on 26 January 2017. The New Nicotine Alliance ("**NNA**") was granted permission to intervene on 26 January 2017.

Parties to the proceedings for the purposes of the reference

Swedish Match

5. Swedish Match is a public limited liability company incorporated in Sweden. Swedish Match does not produce cigarettes; the majority of Swedish Match's sales and profits are derived from smokeless tobacco products ("**STPs**"), including snus.

The NNA

6. The NNA is a registered charity with the objective of promoting public health by means of *'tobacco harm reduction'*, namely reducing harm from cigarette smoking without necessarily giving up the use of nicotine. The NNA focuses on consumer interests and not producer interests. The NNA has no commercial interest in the case and its intervention is made solely in the interest of public and individual health. NNA policies and public statements are evidence-based, with a clear focus on the health of consumers and the wider public and a specific interest to the approximately 8.8 million smokers in the United Kingdom.

The Secretary of State for Health

7. The UK Secretary of State for Health is the Defendant to this claim. He is responsible for implementing the Tobacco Products Directive 2014.

Subject Matter of the dispute

Snus

8. Swedish snus is a smokeless tobacco product made from pasteurised ground tobacco and food-approved additives (table salt, sodium carbonate, humectants, and flavourings). Consumers take a pinch of snus – loose or in a pouch – and place it between their upper lip and gum rather than chewing it. It is mainly sold packaged into small portions in pouches made from non-woven, food-grade material.

9. Snus production is strictly regulated in Sweden as a food product, meaning that all ingredients and flavourings must be food approved and that snus must be manufactured in hygienically controlled facilities suitable for food products. Further to this, the

Swedish National Food Agency has adopted strict rules on maximum levels of undesirable substances in snus.

Regulation of oral snus in the UK prior to 1992

10. In December 1989, the Oral Snuff (Safety) Regulations 1989 were made by the Secretary of State for Health in response to the introduction into the UK in 1984 of a type of moist snuff, manufactured by United States Tobacco International Inc ("**US Tobacco**") and marketed as 'Skoal Bandits'. In light of the uncertainty surrounding the impact of oral snuff on health and the perceived risks to adolescents in particular, the Oral Snuff (Safety) Regulations set a timetable for the eventual prohibition of the sale of oral snuff in the United Kingdom.

11. In December 1990, an application by US Tobacco for judicial review of the Secretary of State's decision was granted and the Oral Snuff (Safety) Regulations were quashed on the basis that while subordinate legislation banning the product on ground of health risk was within the minister's powers, the Secretary of State had a duty to consult US Tobacco before making the Regulations and fairness required that US Tobacco be given an opportunity to make representations[1]. The UK Government did not attempt to re-introduce a national ban on tobacco for oral consumption until Directive 92/41 came into effect on 1 January 1993.

Regulation of snus within the EU

12. The sale within the EU of tobacco for oral use was first prohibited in 1992, by Directive 92/41 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products ("**Directive 92/41**"). This Directive sought to harmonise rules across the EU given that three Member States had already moved to ban tobacco for oral use.

13. Directive 92/41 inserted a new article 8a into Directive 89/622 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labeling of tobacco products ("**Directive 89/622**"). Article 8a stated that "*Member States shall prohibit the placing on the market of tobacco for oral use*", as defined in Article 2(4). Article 2 (4) defined tobacco for oral use as:

> "*all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms — particularly those presented in sachet portions or porous sachets*

[1] *R v Secretary of State for Health, Ex Parte United States Tobacco International* [1992] QB 353 (pp. 369H-370A, B-E, 371F-H, 372H-373B, 376D-G).

— or in a form resembling a food product."

14. Snus falls within this definition of tobacco for oral use. However, the terms of the definition mean that whereas snus is subject to an outright ban, chewing tobacco and nasal snuff can be sold within the EU.

15. On 1 January 1995, Sweden acceded to the EU together with Austria and Finland. Under Article 151 of the Act of Accession, Sweden obtained an exemption from the prohibition in Article 8a of Directive 89/662 (as amended by Directive 92/41) because of the traditional and established use of this product, particularly in Scandinavia. The terms of this exemption meant that, within the EU, tobacco for oral use, as defined in Article 2(4) of Directive 89/662, could only be placed on the market in Sweden.

16. In 2001, Directive 89/622 was replaced by Directive 2001/37, (the **"2001 TPD"**). The 2001 TPD renewed the prohibition of placing tobacco for oral use on the market in Member States other than Sweden, via Article 8 of the 2001 TPD. The definition of tobacco for oral use was the same as in the previous Directive. The 2001 TPD contained no new reasons for maintaining the prohibition, but simply referred back to the ban in Directive 89/622.

17. In 2005, the Directorate-General for Health and Food Safety (**"DG SANCO"**) of the European Commission requested the EU Scientific Committee on Emerging and Newly Identified Health Risks (**"SCENIHR"**) to evaluate the health effects of smokeless tobacco products (**"STPs"**) in order to obtain a better understanding of the health effects of various STPs and their role in smoking cessation and initiation. On 6 February 2008, SCENIHR adopted its report (**"the SCENIHR Report"**).

18. The Commission consulted on options for a revised Tobacco Control Directive between 24 September 2010 and 17 December 2010. The Commission's public consultation document set out the Commission's position in respect of smokeless tobacco products, as it was then:

> "The current regulatory framework bans some smokeless tobacco products ("snus") while others (e.g. chewing tobacco) are freely available in many Member States.
>
> All smokeless tobacco products are addictive and can cause cancer. They also increase the risk of death after a myocardial infarction and may have additional cardiovascular effects as stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008.
>
> For an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related

diseases. It has also been proposed that the use of these products could be a way to quit smoking, but at this moment there is not enough scientific evidence available on the efficacy of snus as quitting aid. On the contrary, as all tobacco products, snus causes dependence and according to the evidence from some countries, the use of smokeless tobacco products may lead to subsequent cigarette smoking".

and proposed three options for future regulation:

"Option 1 - No change

The prohibition on the marketing of tobacco for oral use ("snus") remains unchanged. Other smokeless tobacco products that are perceived as marginal products can continue to be marketed in all Member States.

Option 2 - Lifting the ban on snus

All types of smokeless tobacco products would be freely marketed in the EU, subject to possible requirements for appropriate consumer information such as health warnings.

Option 3 - Ban on all types of smokeless tobacco products

The ban on "snus" would be extended to all types of smokeless tobacco products.
"

19. Following the consultation, on 19 December 2012, the Commission published a proposal for a revised Tobacco Products Directive together with its Impact Assessment ("**IA**"). The proposal suggested renewing the ban on placing tobacco for oral use on the market, stating that from an internal market perspective it was not considered justified to lift the current ban.

20. The Commission further added that the European Court of Justice (**"ECJ"**) [2] had considered the ban proportionate "*due to the harmful effects of oral tobacco, the uncertainty of oral tobacco as a substitute for FMC* [Factory Manufactured Cigarettes], *the addictive and toxic properties of nicotine, oral tobacco's risk potential for young people and the novelty of the product*"[3], and that such reasoning was still valid.

21. On 18 December 2013, the Council and the Parliament agreed on the final text of the new directive, which was adopted on 3 April 2014 as the 2014 TPD.

22. With regard to tobacco for oral use, the EU legislators agreed to renew the ban for the reasons set out in Recital 32 of the 2014 TPD.

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[2] Case C-210/2003 *R (on the application of Swedish Match AB and Swedish Match UK Ltd) v Secretary of State for Health [2004]*

[3] Page 76 of the Impact Assessment (http://ec.europa.eu/health//sites/health/files/tobacco/docs/com_2012_788_ia_en.pdf), citing Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825 paras 44- 56 at footnote 311

"[t]he prohibition of the sale of tobacco for oral use should be maintained in order to prevent the introduction in the Union (apart from Sweden) of a product that is addictive and has adverse health effects. For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use."

23. Article 17 prohibits the placing on the market of tobacco for oral use, but maintains the Swedish exemption. Snus is covered by the definition of "tobacco for oral use" in Article 2(8) of the Directive:

"'tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets".

Regulation of snus within the United Kingdom after 1992

24. On 15 May 1992 Directive 92/41, amending Directive 89/622, came into force. The new Article 8a, prohibiting the placing on the market of tobacco for oral use, was put into effect in the UK via the The Tobacco for Oral Use (Safety) Regulations 1992, which came into force on 1 January 1993.

25. The 1992 Regulations were replaced in May 2016 by the TRP Regulations in order to implement the new TPD. The TRP Regulations were laid before Parliament on 22 April 2016 and entered into force on 20 May 2016. Regulation 17 of the TRP Regulations provides that "*no person may produce or supply tobacco for oral use*".

26. "Tobacco for oral use" is defined in Regulation 2 as:

"a tobacco product which is—

(a) intended for oral use, unless it is intended to be inhaled or chewed; and
(b) *in powder or particulate form or any combination of these forms, whether presented in a sachet portion or a porous sachet, or in any other way*".

The regulation of novel tobacco products and e-cigarettes in the 2014 TPD

27. Novel tobacco products are also regulated within the 2014 TPD. Article 2(14), defines "novel tobacco product" as:

"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".

28. According to Article 19 of the 2014 TPD, Member States must require manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of the Member States six months before the intended placing on the market of such a product. The notification must be accompanied by available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, market research on the preferences of various consumer groups, and other available and relevant information, including a risk/benefit analysis of the product, and its expected effects on cessation and initiation of tobacco consumption.

29. Electronic cigarettes are also regulated by the 2014 TPD. As set out in Article 20(1) of the new TPD, electronic cigarettes and refill containers are regulated in that Directive, unless they are subject to Directive 2001/83, on the Community code relating to medicinal products for human use, or Directive 93/42, concerning medical devices. According to Article 20(2), six months before the intended placing on the market, manufacturers and importers of electronic cigarettes and refill containers must submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market.

30. Article 20 also sets out a number of requirements that the Member States have to fulfill with regard to electronic cigarettes:

    i. Certain product standards are specified including that e-cigarettes are constructed and protected to prevent inadvertent contact with nicotine liquid, that only ingredients of high purity are used, and restrictions on size of containers and strength of nicotine containing e-liquid Article 20(3);

    ii. The unit packs shall carry the health warning "*This product contains nicotine which is a highly addictive substance.*" (Article 20(4)), instructions for safe use, contra-indications, possible adverse effects and warnings for specific risk groups;

    iii. Member States must require manufacturers and importers of electronic cigarettes and refill containers to submit annual data on sales volumes and consumer preferences. Member States are required to monitor market developments, and any evidence that use of electronic cigarettes is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers (Article 20(7));

iv. Member States must require manufacturers, importers and distributors to maintain a system for collecting information about all of the suspected adverse effects on human health of these products (Article 20(9)); and

v. Where a competent authority ascertains or has reasonable grounds to believe that a product could present a serious risk to human health, it may take appropriate provisional measures, of which it shall immediately inform the Commission (Article 20(11)). The Commission is then required to determine whether the provisional measure is justified.

The arguments of the parties

Swedish Match

31. Swedish Match considers that the blanket ban placed on the marketing of snus in the United Kingdom, imposed by Regulation 17 of the TRP Regulations in implementation of Article 17 of 2014 TPD, is not compatible with EU law. The reasoning of the ECJ in the earlier judgment C-210/03 *The Queen on the application of Swedish Match AB v Secretary of State for Health* [2004] ECR I-11893 is no longer applicable given the altered statutory and evidential position that now prevails.

Articles 1(c) and 17 of 2014 TPD are in breach of the EU general principle of non-discrimination

32. The 2014 TPD introduces differential treatment against snus in many ways. As the only tobacco product subject to an outright ban, it is treated much less favourably than the following products that can be marketed subject to regulation under 2014 TPD: (1) other SMTs (Article 2(5)-(7) and (14)); (2) novel tobacco products (see Article 2(14)); (3) cigarettes and other tobacco products for smoking (see Article 2(9) and the specific definitions at Article 2(2)-(3) and (10)-(13)); and (4) electronic cigarettes (see Article 2(16)).

33. The introduction and express regulation of electronic cigarettes and novel tobacco products by the TPD 2014 undermines any justification advanced for the continuing prohibition of snus. Snus is the only form of tobacco product that is subject to a marketing ban within the EU. The ban constitutes unlawful discrimination in that there is nothing about snus that justifies a total ban as against other forms of tobacco products regulated under TPD 2014.

34. Furthermore, the ban cannot be justified on public health grounds: extensive scientific evidence, that was not available when the predecessor regimes were adopted, but that was available and known to the relevant expert bodies when the 2014 TPD was adopted, demonstrates clearly that, both in general and specifically in comparison to other STPs, snus is at the lower end of the risk scale in terms of adverse health effects. There has also been further significant work to limit substances with potential adverse health effects in snus since the adoption of the 2001 TPD. Nor is there evidence that supports the proposition that snus is a 'gateway' to smoking. On the contrary, the available evidence strongly suggests a correlation between the marketing of snus in Sweden and low levels of smoking, particularly for men.

35. The ban also can no longer be justified on the basis of novelty, as novel tobacco products are now subject to specific regulation, but not banned, within the TPD 2014. This is despite the novelty of such products, lack of scientific track record and potential adverse health effects.

36. Nor can it any longer be justified on the basis that snus is produced for the mass market when other products falling within the scope of 2014 TPD are not: other STPs, e-cigarettes and novel tobacco products are extensively marketed throughout Europe.

The outright ban on the marketing of snus outside Sweden is contrary to the general principle of EU law of proportionality.

37. It is not clear from the preamble to the Directive or the impact assessment carried out by the Commission or any other document submitted to the Court why an outright ban on the marketing of snus is either necessary or appropriate to any legitimate public policy objective. The current scientific evidence on the impact of snus on health, in particular its role in decreasing the use of cigarettes does not justify the continuation of an outright ban. Indeed the SCENIHR Report indicated that snus posed a substantially ***lower*** health risk than cigarette use; there was no support for the theory that snus provides a gateway to cigarette smoking; and the availability of snus in Northern Sweden might in fact be beneficial to public health given the numbers that have quit smoking for snus.

38. The nature and extent of the risks associated with oral tobacco are well understood, therefore it is not possible to rely on the 'precautionary approach' in order to justify the total ban on snus. Nor is the approach to snus consistent with the approach to other

tobacco products. There is no justification for a ban on snus on the grounds of protecting public health in policy making (per Article 114(3) TFEU), where the 2014 TPD allows the marketing under regulation of other products, such as chewing tobacco and cigarettes, which the present scientific evidence show are equally or significantly more dangerous to health than snus.

Articles 1(c) and 17 of the 2014 TPD are in breach of the principle of subsidiarity

39. The imposition of an outright ban by the EU legislator removes any regulatory discretion from the Member States and imposes a uniform regulatory outcome regardless of the individual circumstances of the Member States (other than Sweden). This is not a necessary approach, as is clear from the 2014 TPD itself: in respect of all other products falling within its scope, the EU legislator recognizes that the objectives of the proposed action can be sufficiently achieved by the exercise of regulatory discretion by the individual Member States. Articles 1(c) and 17 are therefore contrary to Article 5(3) TEU and the principle of subsidiarity.

Articles 1(c) and 17 of the 2014 TPD are in breach of the duty to give reasons.

40. Article 296 (2) TFEU requires measures adopted by the EU institutions to state the reasons on which they are based. At no point in the 2014 TPD is an explanation given for the discriminatory ban on snus, nor is it clear from the context, given that STPs, e-cigarettes, novel tobacco products and cigarettes can all be marketed within the EU subject to regulation.

The ban on the marketing of snus outside Sweden constitutes an unjustified restriction on free movement of goods.

41. Articles 34 and 35 TFEU prohibit quantitative restrictions on imports and exports between Member States, or measures of equivalent effect, unless under Article 36 these restrictions can be justified on the grounds, *inter alia*, of protecting health and life of humans. Although the protection of human health has been accepted as the primary policy objective justifying restrictions on freedom of movement, such restrictions are nonetheless subject to the general principles of non-discrimination, proportionality and the duty to state reasons for the restriction at issue. The differential ban on snus cannot be objectively justified or proportionate by reference to public health or any other policy ground.

The claim has not been determined by earlier judgments of the ECJ

42. The claim raises distinct legal and evidential issues from the three earlier challenges to the 2014 TPD, Case C-358/14 *Poland v. Commission* (menthol cigarettes); Case C-477/14 *Pillbox 38* (electronic cigarettes); and C-547/14 *Philip Morris v. Commission* (a general challenge to the directive). None of these cases concerned Articles 1(c) or 17 or the ban on snus.

43. With regard to Case C-210/03 *The Queen on the application of Swedish Match AB v Secretary of State for Health* [2004] ECR I-11893, the ECJ rejected a challenge to the validity of the earlier ban on oral tobacco imposed by Article 8 of Directive 2001/37. However, that judgment is not determinative of the present case as there have been extensive changes of relevant circumstances since that judgment: the recent scientific evidence upon which the Claimant relies undermines the assumptions as to the harmful effects of snus made in the earlier judgment; there are significant statutory differences between TPD 2014 and the 2001 Directive; and there have been extensive changes to the market for tobacco products since the judgement in 2004.

The NNA

44. The NNA submits that the ban on snus is disproportionate. It is an unsuitable means by which to achieve the aim of public health protection because it removes from consumers who wish to avoid cigarettes and other combustible tobacco products the option to use a safer product. The rapid rise in the popularity of electronic cigarettes, a grass roots consumer driven phenomenon, shows that smokers want to avoid smoking-related harms. There is the potential to reduce smoking when acceptable products are available to consumers; such uptake being at no cost to public funds.

45. NNA contends that for smokers, and for improving the health of the public, snus fulfils the criteria for a tobacco harm reduction product and hence should be available in the UK. The introduction of snus into the United Kingdom would form part of a coherent strategy of tobacco harm reduction alongside other existing measures to reduce smoking. The current scientific evidence, and the fact that Sweden, where snus is used, now has the lowest lung cancer and tobacco-related mortality in Europe, indicates that snus is a suitable and appropriate product for individuals who are seeking to avoid smoking and other combustible tobacco products.

46. The NNA also submits that the ban on snus engages Articles 1 (human dignity), 7 (respect for private and family life) and 35 (health care) of the EU Charter of Fundamental Rights ("**CFR**"). Article 35 stipulates that a high level of human health

protection shall be ensured in the definition and implementation of all the Union's policies and activities. In violation of Article 35, by banning tobacco for oral use, the EU prevents access to a product that significantly reduces harm to consumers as compared to cigarettes, obliging those who do not succeed in stopping to use nicotine by available means, to continue smoking cigarettes, a product much more harmful to human health than snus.

47. The availability of snus is also an aspect of personal health, where individual consumers can make choices as an aspect of their personal autonomy. A ban on tobacco for oral use limits smokers' choice of safer alternatives, by excluding a product that is significantly less harmful to health than cigarettes. Such a ban is therefore contrary to Articles 1 and 7 of the Charter.

The Secretary of State for Health

48. TPD2014 was published in the Official Journal on 29 April and the Secretary of State had until 20 May 2016 to implement it in accordance with Article 288 TFEU. He originally resisted this judicial review claim on the basis that it was outside the time limit provided for in the domestic rules of procedure (Civil Procedure Rules, Part 54, rule 54.5(1)), but the Administrative Court rejected this argument. In the light of the Administrative Court's ruling, the Secretary of State accepts that a preliminary reference should be made since (i) the EU institutions that were directly involved in the legislative process are better placed to defend the validity of Article 17 of TPD 2014, (ii) the Secretary of State is not in a position himself to adduce evidence and submissions before the Administrative Court to demonstrate that Swedish Match's challenge to the validity of Article 17 is unarguable, and (iii) only the CJEU has the power to declare that a Directive or part of it is invalid.

Reasons for the request for a preliminary ruling

49. Pursuant to Article 267 TFEU, the ECJ has exclusive jurisdiction to determine the validity of EU measures. Given that Regulation 17 implements Article 17 of 2014 TPD, a challenge to the legality of Regulation 17 necessarily involves a challenge to the validity of Articles 1(c) and 17 of 2014 TPD and necessitates a preliminary ruling by the ECJ before the domestic judicial review proceedings can be resolved.

50. On the basis of the written and oral submissions of the parties, the court is satisfied that this application raises genuine concerns about the validity of the continuing ban on oral

tobacco and that a ruling by the ECJ is necessary to enable the national court to reach a judgment.

Questions for reference

51. The following questions are referred to the ECJ:

"Are Articles 1 (c) and 17 of Directive 2014/40/EU invalid by reason of:

i. Breach of the EU general principle of non-discrimination;
ii. Breach of the EU general principle of proportionality;
iii. Breach of Article 5(3) TEU and the EU principle of subsidiarity;
iv. Breach of Article 296 (2) of the Treaty of the Functioning of the European Union ("TFEU");
v. Breach of Articles 34 and 35 TFEU; and
vi. Breach of Articles 1, 7 and 35 of the EU Charter of Fundamental Rights.