

EXPLANATORY MEMORANDUM TO
THE TOBACCO AND RELATED PRODUCTS REGULATIONS 2016
2016 No. 507

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 The Tobacco and Related Products Regulations 2016 implement the majority of provisions of the revised Tobacco Products Directive 2014/40/EC to:
- Continue, and enhance in some areas, the reporting of ingredients and emissions of tobacco products;
 - Increase the size of combined health warnings consisting of a text and photograph warning, increased in size to cover 65% of front and back of pack (previously 30% on front of pack and 40% on back of pack);
 - Prohibit misleading descriptors, such as “natural” or “organic” on tobacco and electronic cigarette labelling;
 - Prohibit characterising flavours such as menthol in tobacco products;
 - Provide for prior notification of the placement of novel tobacco products on the market;
 - Regulate electronic cigarettes and associated refill cartridges (notification of placing on the market, adverse event monitoring, product standards, labelling and advertising);
 - Regulate herbal cigarettes (notification of placing on the market and labelling).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 At the time of making this instrument, the Tobacco Products Directive 2014/40/EC has not yet been incorporated into the EEA Agreement. However the e-commerce directive 2000/31/EC has been incorporated into the EEA Agreement. That is reflected in regulations 43(2) and (3), which implement Article 3 of the e-commerce directive in relation to e-cigarette advertising in information society services.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. **Legislative Context**

- 4.1 The Tobacco and Related Products Regulations 2016 (the ‘Regulations’) transpose the revised Tobacco Products Directive 2014/40/EC (the ‘Directive’) with the exception of Articles 6 establishing a priority list of additives and enhanced reporting obligations, 15 and 16 on Track and Trace and Security features and Articles 9.3 (3rd indent) 13 and 14 on product presentation and appearance and content of unit packets. Article 6 will be implemented by means of an amendment, as the associated implementing act is not adopted at the time of making these Regulations. Articles 9.3 (3rd indent) 13 and 14 of the Directive are implemented through the Standardised Packaging of Tobacco Regulations 2015 (SI 2015/829). Articles 15 and 16 will be implemented, by HMRC, through separate legislation when more detail is set out in further EU legislation expected in 2017.
- 4.2 The Regulations also implement tertiary legislation under the Directive made by the European Commission since its adoption under delegated and implementing powers. That legislation is listed in the Explanatory Note to the Regulations.

Scrutiny History

- 4.3 The European Commission’s proposed revision to Directive 2001/37/EC (The first Tobacco Products Directive) was published in December 2012. The text was deposited for scrutiny by the European Scrutiny Committees of both houses in January 2013 and held under scrutiny reserve during negotiations.
- 4.4 The final text of the Directive was cleared by the House of Commons Scrutiny Committee, following debate, in December 2013. However the Government accepted changes to the text during trilogue following rejection by the EU Parliament of text that required medicinal licencing for the majority of e-cigarettes. This resulted in a compromise text that allows products that are not medicines, to be sold as consumer products and covered by specific safety and quality standards in the Directive. A further updated Explanatory Memorandum was deposited in both Houses. The House of Commons European Scrutiny Committee cleared the final proposed text on 29 January and the House of Lords did so on 5 February 2014.
- 4.5 In accordance with the ordinary legislative procedure the revised Directive was adopted at first reading by the Council on 14 March 2014 following its formal approval by the European Parliament on 26 February 2014 and published in the Official Journal of the European Union on 29 April 2014. The text is required to be transposed into domestic legislation by 20 May 2016.

Approach to transposition

- 4.6 A minimal approach to transposition has been taken. The Government has gone further than the minimum requirement of the Directive in respect of the labelling of tobacco products other than cigarettes, roll your own tobacco and waterpipe tobacco. The Directive allows for a lesser health labelling regime for these products, excluding the use of picture warnings and an information message. Picture warnings are already required in the UK for all tobacco products except for single wrapped cigars and cigarillos. To derogate tobacco products other than cigarettes, hand rolling and waterpipe tobacco from carrying pictorial health warnings, as the Directive allows for, would reduce existing health protection measures in the UK. The Regulations therefore require the full labelling regime i.e. larger picture warnings, information and

general warnings, set out in the Directive for all tobacco products except cigars and cigarillos sold individually by the piece and cigars weighing more than 3g.

- 4.7 A transposition note is attached at Annex A.

Enforcement

- 4.8 The majority of the Regulations will be enforced by Trading Standards Officers (or Environmental Health Officers in Northern Ireland). These agencies are currently designated as enforcement authorities for existing labelling and consumer protection standards for the categories of product covered by the Regulations.
- 4.9 The rules for advertising electronic cigarettes will be enforced by the agencies which currently enforce the rules on tobacco advertising. OFCOM will enforce the rules for broadcast media and trading standards will enforce the non-broadcast media rules with the Advertising Standard Authority undertaking a first line self-regulatory check on the industry.

5. Extent and Territorial Application

- 5.1 The Tobacco and Related Products Regulations 2016 extend to all of the United Kingdom.
- 5.2 The Tobacco and Related Products Regulations 2016 apply to all of the United Kingdom.

6. European Convention on Human Rights

- 6.1 Parliamentary Under Secretary of State for Public Health Jane Ellison MP has made the following statement regarding Human Rights:

The Tobacco and Related Products Regulations 2016 amend primary legislation; in my view the provisions are compatible with the Convention rights.

7. Policy background

What is being done and why

- 7.1 The Tobacco Products Directive 2014/40/EU updates and repeals Directive 2001/37/EC which contained rules that were out of date and did not reflect new market, scientific and international developments. Both the European Council and the European Parliament were keen to see further regulation of tobacco products which account for health costs in excess of €25 billion per year and are the most significant cause of premature deaths in the EU; responsible for almost 700,000 deaths every year.
- 7.2 The main provisions of the Directive, that are implemented by these Regulations are listed at para 2.1 of this document. In addition Articles 15 and 16 provide for a track and trace system and new security features. These provisions will be implemented, by HMRC, through separate regulations when the necessary detail is set out in further EU tertiary legislation. The Directive introduces rules for herbal products for smoking and electronic cigarettes and refill containers which are not yet covered by European harmonisation measures, but are products for which Member States were likely or had already developed different rules with a risk of fragmentation of the internal market.
- 7.3 The revision of the Directive will also assist Member States to meet their international obligations under the International Framework Convention on Tobacco Control.

- 7.4 The European Commission estimates that the Directive will have reduced smoking prevalence rates by between 1.7% and 2.6% five years after transposition. The UK has pursued the public health agenda more thoroughly than some other Member States – notably on requiring picture warnings for unit packets of cigarettes since 2008. It is therefore expected that in the UK the reduction in smoking prevalence attributed to the Directive will be in the range of 1.7% - 2.1% from the current level of 18.3% (UK 2015). This equates to around 200,000 fewer smokers and lifetime health benefits of £13.7 billion.

Consolidation

- 7.5 The Tobacco and Related Products Regulations 2016 will revoke the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (as amended) subject to regulation 10 which requires product identification markings on tobacco products. This requirement will be maintained until the new track and trace provisions come into force in 2019 for cigarettes and roll-your-own/hand rolling tobacco and 2024 for other tobacco products. The Tobacco for Oral Use (Safety) Regulations 1992 will also be revoked.

8. Consultation outcome

- 8.1 A nine week consultation was undertaken from 2 July to 3 September 2015. The Government consulted on draft regulations and its proposed approach to the derogations set out on the face of the Directive. A draft Impact Assessment accompanied the consultation. The government received 709 responses, the majority (75.6%) from the public.
- 8.2 Further stakeholder engagement on the further rules proposed by the Commission, as provided for in the Directive, was conducted as proposals were made available and engagement on the proposed implementation of the restrictions on advertising for e-cigarettes was undertaken from 23 November 2015 until 4 January 2016.
- 8.3 Stakeholders were broadly supportive of the Government’s recommended approach to transposition, however the tobacco industry, electronic cigarette industry and vaping community (users of e-cigarettes) continued to voice concern about the effect of the Directive and its legality. The advertising sector questioned the Government’s interpretation that banned advertising in local newspapers, TV and radio broadcasts within the UK but stakeholders accepted a minimal approach had been taken to transposition of the e-cigarette advertising provisions.
- 8.4 As a result of the consultation and stakeholder engagements the Government made the following choices in response to the options provided to Member States in the Directive:
- to require peer review of reports submitted by the tobacco industry in relation to certain additives present in tobacco products (to be implemented separately on adoption of tertiary legislation).
 - to adopt ‘Smoking Kills – Quit Now’ on tobacco products and ‘This product contains nicotine which is a highly addictive substance’ on e-cigarettes and not the longer warning ‘This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers’.

- to derogate cigars and cigarillos sold individually by the piece and cigars weighing more than 3g from the full requirement to label with picture warnings.
- to put in place a registration scheme for cross-border sales of tobacco products and e-cigarettes rather than ban such sales.
- to introduce a notification scheme rather than an authorisation system for novel tobacco products.
- to adopt proportionate fees to recover, from businesses, Government costs in complying with the requirements of the Directive (these will be introduced in separate legislation by MHRA for e-cigarettes and DH for tobacco products).
- to apply a 12 month transition period to allow the sell through of old stock at retail.

8.5 The Government also received comments on the draft legislation and as a result amended the legislation to:

- not take forward provisions to require businesses to name an individual responsible for gathering adverse event information on e-cigarettes.
- limit the restrictions on the use images of tobacco products to those associated with the sale of the tobacco products illustrated. The implementing regulations are compatible with the right to freedom of expression, and does not prevent the use of images of tobacco product, that are not compliant with the regulations in research, the media or other publications, for illustrative purposes.
- make provision (until the new track and trace requirements take effect in 2017/2024) for code markings that allow the identification of the place, date and in the case of a product other than cigars, the time, of manufacture to be determined.
- make clear that there is no legal requirement on the positioning of the general and information warnings other than on cigarette and hand rolling tobacco packaging.
- make clear that in submitting data on novel tobacco products only studies that are available at the time of submission are required and that manufacturers are not required to do additional studies on toxicity, addictiveness, attractiveness or undertake additional market research.
- align the terminology in the UK implementing regulations with that in the further tertiary legislation that had been published since the time of the consultation.
- limit the offence of supplying false and misleading information to persons doing so knowingly or recklessly.
- make clear that advertising covered by the Regulations must be undertaken in the course of a business and to provide for a specific publisher's defence.

8.6 Full details of the consultation and the Government's response can be found at: <https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products>

9. **Guidance**

- 9.1 The Department of Health has worked with the Chartered Trading Standards Institute to cascade training on the Regulations to enforcement officers across the UK. An e-learning module has also been developed to support this work. This will be supplemented by further guidance on labelling of tobacco products under the Standardised Packaging of Tobacco Products Regulations 2015.
- 9.2 The Commission has developed guidance on the Directive's labelling requirements and Public Health England and Medicines and Health products Regulatory Agency will be providing guidance on the notification requirements and support to businesses in the initial stages of the scheme.

10. **Impact**

- 10.1 The impact on business is estimated at £16.4 million per year. The largest cost is the loss of profits due to reduced smoking prevalence as a result of the measures in the Tobacco and Related Products Regulations 2016 which impact on initiation of smokers and intention to quit. Other costs include relabelling of tobacco products and e-cigarettes to comply with new requirements, costs of notifying tobacco products and e-cigarettes and loss of profits to the advertising industry as a result of the restrictions on e-cigarette advertising.
- 10.2 There is no significant impact on the public sector. The costs to the Medicines and Health products Regulatory Agency, Public Health England and the Department of Health of meeting the requirements of the Directive will be recoverable from businesses and are accounted for above. Enforcement Authorities already deal with legislation on tobacco products and that related to product safety and description. Additional costs have been identified relating to familiarisation of the new provisions, activities to bring businesses into compliance and new provisions of the directive, for example e-cigarettes and herbal tobacco products. A New Burdens Assessment has been agreed by Department for Communities and local Government, and final funding will be agreed pending the outcome of the EU legal challenges on the lawfulness of the Directive.
- 10.3 An Impact Assessment, scrutinised by the Regulatory Policy Committee and passed fit for purpose on 26 January 2016 is submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. **Regulating small business**

- 11.1 The legislation applies to activities that are undertaken by small businesses.
- 11.2 The health benefits identified, or the improvement in market functioning due to harmonisation across the EU, could not be realised by exempting small businesses from the regulations as they depend on consistent application. Whilst most aspects of the Directive apply to organisations of all sizes, small businesses are exempt from the requirements of Article 6 (submitting detailed studies on priority additives), if the relevant additive is being studied by another organisation. The Department of Health will ensure information on the studies being undertaken by larger organisations is freely available. This will help to reduce costs to small businesses.
- 11.3 The Government's choice not to ban cross border distance sales is also likely to benefit small specialist distributors who may continue to have wider access to the EU markets that continue to allow cross-border sales.

11.4 The Government has also chosen to allow a sell through period until May 2017 that will be of most benefit to small tobacco and electronic cigarette retailers.

11.5 Exempting cigars and cigarillos sold individually by the piece and cigars weighing more than 3g from the full labelling requirements will reduce the cost burden on manufacturers, importers, distributors and retailers, some of which will be small businesses.

12. **Monitoring & review**

12.1 The European Commission is charged with reviewing the Tobacco Products Directive by 20 May 2021. The Regulations contain a commitment to review within 5 years in accordance with sections 28-32 of the Small Business Enterprise and Employment Act 2015. Alongside a range of Government, commercial and third sector data collection tools that provide data on smoking rates, access to, and patterns of use of, tobacco products and e-cigarettes, the evaluation will be informed by data generated by the reporting requirements in the Regulations themselves, including ingredient and emission information, market survey and sales data.

12.2 The Department is also committed to including within the forthcoming Tobacco Control Plan, a holistic review of the enforcement regime for all Department of Health tobacco legislation and look at further use of civil penalties where appropriate, to avoid unnecessary criminal offences.

13. **Contact**

13.1 Alette Addison at the Department of Health (Tel: 020 7972 4858 or e-mail: alette.addison@dh.gsi.gov.uk) can answer any queries regarding the instrument.