EXPLANATORY MEMORANDUM TO

THE TOBACCO AND RELATED PRODUCTS (AMENDMENT) REGULATIONS 2016

2016 No. 1127

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.

2. Purpose of the instrument

2.1 The Tobacco and Related Products (Amendment) Regulations 2016, transpose Commission Implementing Decision (EU) 2016/787 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations. This is enacted by amendment to the Tobacco and Related Products Regulations 2016.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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 On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU

4.2 The Tobacco and Related Products (Amendment) Regulations 2016 (the 'amendment Regulations') amend the Tobacco and Related Products Regulations 2016. The amendment Regulations transpose Commission Implementing Decision (EU) 2016/787 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations (the 'Decision').The amendment Regulations also transpose Article 6 of the revised Tobacco Products Directive 2014/40/EC (the 'Directive'), which lays down reporting obligations for producers of products containing substances on the priority list of additives and can be transposed now that the priority list has been published.

Scrutiny history

4.3 Commission Implementing Decision (EU) 2016/787 was adopted on 18 May 2016, and published in the Official Journal of the European Union on 20 May 2016.

4.4 The Decision was not deposited for scrutiny in either House in accordance with advice from the Secretariat of both scrutiny committees.

Approach to transposition

4.5 A minimal approach to transposition has been taken and no flexibilities are available to Member States. A transposition note is attached at Annex A.

Enforcement

4.6 The Regulations will be enforced by the Secretary of State.

5. Extent and Territorial Application

5.1 The extent of this instrument is the United Kingdom.

5.2 The territorial application of this instrument is the United Kingdom

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 The Department transposed most of the revised Tobacco Products Directive 2014/40/EU ("the Directive"), via the Tobacco and Related Products Regulations 2016 (TRPR), which was laid on 22 April and entered into force on 20 May 2016. On 20 May 2016, a tertiary act was published in the Official Journal – Commission Implementing Decision (EU) 2016/787 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations; it is required to be transposed by 1 January 2017. Decision 2016/787 and Article 6 of the Directive will be transposed via a technical amendment to the TRPR.

7.2 The implementing Act, combined with the provisions of Article 6 of the Directive, establish a list of 15 additives used in the manufacture of cigarettes and roll-your-own (hand rolling) tobacco where either safety concerns exist, or where the addition of these additives might give the tobacco a "characterising flavour" suspected of facilitating initiation of smoking. Such characterising flavours are prohibited under the Directive. The substances on the list have been selected by the European Commission with the assistance of the Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) on the basis of available data suggesting that an additive may:

- contribute to toxic, addictive or carcinogenic, mutagenic or reprotoxic properties ('CMR properties') of cigarettes and roll-your-own tobacco;
- result in a characterising flavour; or
- facilitate inhalation or nicotine uptake.

7.3 Member States are to require manufacturers and importers of cigarettes and roll-your-own tobacco (hand rolling tobacco) to carry out comprehensive studies on any of the 15 additives contained in their products which have been included in the priority list. The results of these studies must be reported to the UK competent authority (Public Health England) within 18 months of the additive being added to the priority list. The 'priority list' applies from 1 January 2017, therefore reports should be submitted by 1 July 2018.

7.4 In transposing these measures the Department has used 'copy out' of the Commission Decision and Article 6 of the Tobacco Products Directive.

8. Consultation

8.1 The Department included in its public consultation of July 2015, details of the provisions in Article 6 of the Directive. This included the Government's intention to require peer review of reports submitted by the tobacco industry in relation to products containing substances on the priority list of additives.

8.2 In addition, the tobacco industry was consulted in the development of the SCENIHR Opinion on the Additives used in tobacco products and resulting draft Decision. The Government informed interested parties of the publication of the Decision on 20 May 2016 and that the UK will amend the TRPR to include the priority list of additives in order to enter into force by 1 January 2017.

9. Guidance

9.1 The European Commission, with assistance from the Scientific Committee on Health, Environmental and merging Risks (SCHEER formerly SCENIHR), is developing guidance on the type and criteria for the comprehensive studies required by producers. Guidance will be made available on the Ec.europa.eu website.

10. Impact

10.1 The impact of Article 6 of the Directive and the Decision is included in the Impact Assessment for the Directive published alongside the Tobacco and Related Products Regulations 2016 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 To minimise the impact of the requirements on small businesses (employing up to 50 people), businesses may produce joint studies and Small and Medium Businesses are exempted from the obligations if a report on an additive is prepared by another manufacturer or importer.

12. Monitoring & review

12.1 The Tobacco and Related Products Regulations, which this measure amends, contains a commitment to review within 5 years in accordance with sections 28-32 of the Small Business Enterprise and Employment Act 2015.

13. Contact

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