EXPLANATORY MEMORANDUM TO

THE STANDARDISED PACKAGING OF TOBACCO PRODUCTS REGULATIONS 2015

2015 No. [XXXX]

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 draft Regulations relate to the retail packaging of hand rolling tobacco and the retail packaging and appearance of cigarettes. These Regulations would require the use of specified standard colours for all external and internal packaging of cigarettes and hand rolling tobacco and would only permit specified text (such as the brand and variant name) in a standard typeface. The draft regulations would not affect other labelling requirements for tobacco products such as health warnings and fiscal marks or features such as authentication markings and security features. The draft Regulations would also permit only specified shape or type of packets and set a minimum amount of tobacco or cigarettes in each individual packet.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 Section 94 of the Children and Families Act 2014 gives the Secretary of State regulation-making powers to make provision about the retail packaging of tobacco products. These regulations are being made to implement a new Government policy on standardised packaging of tobacco products and would be the first exercise of these powers.

4.2 In order to exercise the powers in section 94, the Secretary of State must consider that the regulations may contribute at any time to reducing the risk of harm to, or promoting, the health or welfare of children. In deciding to exercise the powers the Secretary of State has considered this requirement to be fullfilled.

4.3 The European Tobacco Products Directive (TPD) was published in May 2014 and it will need to be implemented by UK legislation by 20 May 2016. The TPD sets out a number of new requirements that will apply to tobacco and related products across the EU. Regulations 4, 8, 10, and 19 of these Regulations would implement Articles 13 and 14, and one element of Article 9.3, of the TPD. Those Articles provide for requirements that relate to

the presentation and appearance of tobacco products and their packaging, along with setting minimum amounts of tobacco or cigarettes per individual packet, and so these Regulations provide the appropriate legislative vehicle for implementation. A Transposition Note is attached at Annex A. The other requirements of the TPD will be transposed in separate regulations that will be made in future.

4.4 These regulations would be enforced by Local Authority Trading Standards (or environmental health officers in Northern Ireland), using their powers under the Consumer Protection Act 1987. These agencies are currently designated as the enforcement authorities for existing requirements for tobacco packaging, such as the requirements for the health warning, product identification markings and products descriptions and other requirements set out in The Tobacco Products (Manufacture, Presentation and Sale (Safety) Regulations 2002 and subsequent related regulations.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

5.2 The primary purpose of standardised packaging is to promote public health, although the regulations also deal with consumer protection, labelling and the single market as well as implementing EU product requirements. Public health is a devolved matter and s94(12) of the Children and Families Act 2014 provides that the Secretary of State obtain the consent of Ministers in each devolved administration before making regulations containing provision which would be within the legislative competence of their respective Parliament or Assembly. Consent has been obtained from Ministers in Scotland, Northern Ireland and Wales.

6. European Convention on Human Rights

The Secretary of State for Health has made the following statement regarding Human Rights:

In my view the provisions of The Standardised Packaging of Tobacco Products Regulations 2015 are compatible with the Convention rights.

7. Policy background

7.1 Tobacco use remains one of the most significant challenges to public health in the United Kingdom. Smoking is the primary cause of preventable morbidity and premature death, accounting each year for over 100,000 deaths in the United Kingdom. One out of two long-term smokers will die of a smoking-related disease. Around 20% of adults in the United Kingdom smoke.

7.2 Smoking is a habit largely taken up in childhood and adolescence. The report of the Chantler Review, an independent review of the evidence on the public health benefits of standardised packaging, concluded that it is '*highly likely that standardised packaging would serve to reduce the rate of children*

taking up smoking' and that the policy would '*very likely lead to a modest but important reduction over time on the uptake and prevalence of smoking and thus have a positive impact on public health'.* The Chantler Report stated that, although the number of children taking up smoking has been falling since the 1990s, an estimated 207,000 children aged 11-15 still take up smoking each year in the United Kingdom. A key aspect in deciding to introduce standardised packaging is the potential benefit for the health and wellbeing of young people.

7.3 The objectives of a policy for standardised packaging include:

- discouraging people from starting to use tobacco products
- encouraging people to give up using tobacco products
- reducing the appeal or attractiveness of tobacco products, the misleading elements of packaging and the potential for packaging to detract from the effectiveness of health warnings
- having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products

7.4 A range of alternative measures to standardised packaging that have been suggested by stakeholders in response to the two public consultations include youth education and school-based programmes on smoking and public information campaigns. Many of these measures are already being implemented but in any event, none go towards reducing the promotional effects or the branding of tobacco packaging. Voluntary measures or codes of practice are not a practical option for this policy which is strongly opposed by the tobacco industry.

7.5 A number of consultation responses, including those from the tobacco industry, have stated that the regulations would be unlawful and in particular that they would breach property rights by depriving tobacco companies of their trade marks. These companies have made it clear that they intend to bring legal challenges to the regulations. The government has considered these legal issues carefully and takes the position that it is lawful to proceed and that these claims will be defensible.

Parliamentary interest

7.6 The amendments to the Children and Families Bill, introducing the relevant regulation-making powers for standardised packaging of tobacco, were voted through Parliament with a large majority.

7.7 There remains strong Parliamentary interest in the policy, which is evidenced by the large number of Parliamentary questions and adjournment debatestabled on standardised packaging over the last year.

Detail of the regulations

7.8 The proposed affirmative regulations would standardise the packaging of all cigarettes and hand rolling tobacco for retail sale by:

- specifying mandatory colours for retail packaging (dull brown for the outside and white for the inside, in line with requirements already in place in Australia);

- permitting only specified text (such as the brand and variant name, number of cigarettes, a barcode and the producer's contact details) and ensure any permitted text conforms to particular requirements such as typeface and size;

- prohibit embossing or irregular shape or texture on the packaging; prohibit the inclusion of any inserts; and require that wrappers are clear and transparent; and

- allowing required markings such as health warnings and fiscal marks (including covert markings and any future requirements that may be introduced to tackle illicit trade) to remain in place.

7.9 Legislation would also implement certain packaging related parts of the European Tobacco Products Directive that was agreed last year, further details of which are provided in the Transposition Note at Annex A.

7.10 The packaging requirements apply to retail packaging (the packaging that is, or is intended to be presented for sale to consumers) and so do not affect packaging that is just used within the trade (i.e. wholesale) nor does it prevent branding or trademarks being used on internal documents or trade magazines or journals.

7.11 The regulations cover only the packaging of cigarettes and hand-rolling tobacco and not specialist tobacco products such as cigars (except for Regulation 10, which applies to all tobacco products and implements a requirement under the new EU Tobacco Products Directive). Data show that the prevalence of cigar and pipe smoking is much lower than cigarette and hand-rolling tobacco smoking, and that a very small number of children and young people use this type of tobacco.

7.12 These regulations would make it an offence to produce or supply tobacco products that have retail packaging that do not meet the provisions set out in the regulations, on the penalty on summary conviction would be imprisonment for a term not exceeding three months, or a fine of any amount, or both, or if convicted on indictment, would be liable to imprisonment for 2 years or a fine or both. These regulations provide for a defence for someone who supplies tobacco products (for instance a small shop keeper), if they neither knew nor had reasonable grounds for suspecting that the tobacco packaging was in breach of the regulations.

7.13 As with many existing tobacco control laws, local authority trading standards officers (or environmental health officers in Northern Ireland) would be responsible for enforcement, using the range of powers under the Consumer Protection Act used to enforce safety regulations.

7.14 The regulations would come into force on 16 May 2016 to coincide with the transposition deadline for the Tobacco Products Directive to minimise burdens on business. The provisions allow for a 12-month sell-through period for old stock that was manufactured before May 2016.

8. Consultation outcome

8.1 The Government has run two public consultations specifically on standardised packaging, in 2012 and 2014. The number of consultation responses received to both consultations was very large primarily due to campaigns being run by interested groups on both sides of the debate.

8.2 The second consultation in 2014 ran for 6 weeks. In determining the consultation period, ministers took into account the Cabinet Office's consultation principles. In particular, they considered the principle that engagement should begin early in the policy development, and that every effort should be made to make the Government's evidence base available at an early stage.

8.3 Stakeholders have had a number of opportunities to express their views and provide evidence, including during the first consultation in 2012 which ran for 16 weeks. The Department of Health also asked Sir Cyril Chantler, an eminent paediatrician, to conduct a review of the evidence on the impact on public health of introducing standardised packaging – the review reported on 3 April 2014. The Chantler review provided interested parties with a further opportunity to make representations. In a statement to the House of Commons on 3 April 2014, Health Ministers invited those with an interest to start considering then any responses to consultation they may wish to make, with an emphasis on any information since 2012. There were twelve weeks from that statement until the start of the 2014 consultation in which stakeholders could have prepared their response.

8.4 In light of all of the above circumstances, six weeks was the appropriate period for the 2014 consultation, being both proportionate and realistic to allow stakeholders sufficient time to provide a considered response.

8.5 In both consultations respondents fell into two distinct groups: 1) Those who supported the introduction of standardised packaging of tobacco products - consisting predominately of health charities, non-governmental organisations, local authorities and their public health and trading standards departments, NHS bodies, and health and social care professionals; and 2) Those who opposed the policy - largely made up of businesses involved in the tobacco industry, retail, design, packaging, intellectual property/trademarks and their relevant trade associations.

8.6 The 2012 consultation received around 2,400 detailed responses that addressed multiple consultation questions and nearly 666,000 campaign responses. Of the detailed responses, 53% favoured the requirement of standardised packaging and 43% favoured doing nothing about tobacco packaging. The other 4% were either neutral or favoured a different option. Of the campaign responses, 36% supported the introduction of standardised packaging and 64% opposed. The 2014 consultation received around 1,300 detailed responses and around 136,000 campaign responses. The 2014 consultation did not ask respondents whether they supported or opposed standardised packaging.

8.7 The main themes identified in the responses to the consultations related to:

- Evidence emerging from the introduction of a similar policy in Australia
- Findings from the Chantler Report
- Potential impact on the illicit tobacco trade
- The effects on smoking prevalence and uptake (particularly by young people)
- The legal implications
- Possible unintended consequences
- Impact on tobacco retailers
- Recommendations for amendments to the set of regulations
- Suggested improvements to the impact assessment calls for wider action on tobacco products and youth smoking

8.8 Arguments were put forward by both opponents and supporters to make their case in relation to these points. Further detail on the responses to consultation is provided in the summary reports on the 2012 and 2014 consultations, which are both available on the DH web site.[1]

9. Guidance

9.1 Guidance will be made available for Local Authority trading standards officers (or environmental health officers in Northern Ireland). It will be developed with relevant bodies responsible for support and training of trading standards officers.

9.2 Further guidance will also be made publically available, before the measures come into force, which can be used by the general public, retailers, UK Border Force and other relevant bodies to increase awareness and understanding of the new requirements.

[1] https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products and https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products-draft-regulations

10. Impact

10.1 The impact on business has been carefully considered and detailed analysis is provided in the Impact Assessment (IA), which is attached to this memorandum at Annex B and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

10.2 The Impact Assessment shows that the policy is expected to decrease smoking in the UK causing hundreds of thousands of fewer premature deaths. This Health Benefit is valued at £29bn. The expected change in smoking will lead to reduced tax valued at £5bn. Various uncertainties and risks are also considered such as that of an increase in the illicit market or cross border shopping (CBS). The Impact Assessment concludes that there is a sizeable likelihood that there will be no increase in the illicit market or cross border shopping, but there is a chance of a small increase valued at £31m.

10.3 The Impact Assessment shows that the policy has a cost to UK business of nearly £37m per year mainly from reduced tobacco sales. However, the policy is also expected to have a benefit to business since businesses will gain from people spending money on other goods and services instead of tobacco. UK industry will also gain from a healthier workforce. When the benefits and costs are considered together, the overall net impact upon business is likely to be positive.

10.4 The Government has not identified any impact on charities, voluntary bodies or on the public sector. Enforcing these regulations will not increase the burden on Local Authorities (or environmental health officers in Northern Ireland), as the requirements will form part of their existing requirements to enforce tobacco packaging legislation.

10.5 An Equality Analysis was completed in accordance with the Secretary of State's Equality Duty and published alongside the Government report on consultation.[2]

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken is to implement the requirements of these regulations at the same time as the transposition deadline for the Tobacco Products Directive (TPD). These regulations would provide for a 12-month sell-through period for old stock that was manufactured before May 2016

[2] https://www.gov.uk/government/consultations/standardised-packaging-of-tobacco-products-draft-regulations

(which is a requirement of the TPD for those Articles that would be implemented by these Regulations). These regulations would also provide for a defence for someone who supplies tobacco products (for instance a small shop keeper), if they neither knew nor had reasonable grounds for suspecting that the tobacco packaging was in breach of the regulations.

11.3 Small business were engaged in the 2012 and 2014 public consultations and the impact on small business is outlined in further detail in the Impact Assessment. Requiring all changes to packaging of tobacco products to be made from one single date will reduce the burden on business, and simplify the postion for retailers and enforcement agencies. The 12 month sell-through period for old stock significantly reduces any risk of small retailers or wholesalers suffering a loss from having to dispose on non-compliant tobacco stock.

12. Monitoring & review

12.1 The Government monitors tobacco legislation on an ongoing basis. Officials will talk to enforcement authorities as the legislation comes into force to see how enforcement is working and a formal requirement to review within 5 years has been included in the regulations.

13. Contact

Jeremy Mean at the Department of Health Tel: 020 7972 4554 or email: jeremy.mean@dh.gsi.gov.uk can answer any queries regarding the instrument.