



Department
of Health &
Social Care

Government response to the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2018 consultation

21 February 2019

Contents

1. Introduction3

2. Consultation Overview4

3. Statistical Overview7

4. Overview of Responses9

 Parts One and Two - Notification systems.....9

 Part Three - Picture Warnings 10

5. Next steps 12

1. Introduction

- 1.1 Current regulations for tobacco and related products are designed to promote and protect the public's health. The government's priority is to maintain the same high standards after the UK leaves the European Union (EU).
- 1.2 In the event of no deal, the United Kingdom's Government has introduced legislation to ensure that the policies and systems in place to regulate tobacco products and e-cigarettes will continue to function effectively and maintain continuity with current arrangements where possible. This approach means that there will be minimal disruption for citizens and businesses in relation to tobacco products and e-cigarettes.
- 1.3 The Department of Health and Social Care (DHSC) in England held a public consultation starting on Monday 8th October until Sunday 21st October.
- 1.4 This document outlines a summary of the consultation responses and the Government's response.
- 1.5 The legislation was made on 10th January 2019, and is therefore now the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2019.

2. Consultation Overview

- 2.1 The Department of Health and Social Care in England held a public consultation from Monday 8th October to Sunday 21st October. The consultation was taken forward in accordance with the Cabinet Office Consultation Principles.
- 2.2 The consultation paper was made available on the gov.uk website.
- 2.3 The background to these regulations is as follows. If the UK leaves the EU in March 2019 with no agreement in place, the Tobacco Products Directive and the Tobacco Advertising Directive would no longer directly apply to the UK.
- 2.4 The UK domestic law that implements these directives, such as the Tobacco and Related Products Regulations 2016, would remain in force, with minor amendments to ensure it still works effectively after EU exit. These amendments would have been brought in through regulations made under the EU (Withdrawal) Act 2018 powers and would come into force on exit day.
- 2.5 The amendments to UK tobacco legislation include giving the UK Government the power to update the legislation in response to emerging threats, changing safety and quality standards, and technological advances. These updating powers are likely to have minimal impact on industry. Their purpose is to make sure that the UK is still able to make technical changes after we leave the EU, where needed.
- 2.6 The consultation set out three practical changes necessary to ensure that the current tobacco control arrangements continue to function in the event of leaving the EU without a deal. In each case change is required because the UK would no longer be able to rely agreeing arrangements with the EU in the event of no deal:
 - a new domestic system to allow producers to notify e-cigarettes in accordance with existing rules (part 1)
 - a new domestic system to allow producers to notify tobacco products in accordance with existing rules (part 2)
 - the introduction of new picture warnings for tobacco products, based on the picture library owned by the Australian government (part 3)
- 2.7 DHSC received 32 responses in total from: individuals, representatives from the tobacco and e-cigarette industry, and tobacco control stakeholders.
- 2.8 Responses were submitted via the digital platform 'Citizen Space' or by email.
- 2.9 Part 1: notification processes for e-cigarettes

- 2.10 Proposed changes to current procedure:
- 2.11 Wherever a product is being sold in the UK, the Government will ask notifiers to upload the notification files to a secure government server. This is in addition to any requirements made by the Tobacco Products Directive (TPD) for notification in the EU. All notifiers will need to register with the UK portal to submit their data.
- 2.12 If a notifier does not wish to submit non-UK market information (points 32 to 46 listed in [TPD submission data dictionary – electronic cigarettes v1.1.1](#)) to the UK, then they should remove that data before submitting to the Medicines and Healthcare products Regulatory Agency (MHRA).
- 2.13 If notifiers are unwilling or unable to submit information in the form set out above, then they will be required to complete an online form including all relevant data points, excluding points 32 to 46, listed in [TPD submission data dictionary – electronic cigarettes](#). This will also allow any required attachments to be submitted along with the form.
- 2.14 Notifiers will be required to provide details of a responsible UK entity if this information is not currently provided via the European Union - Common Entry Gateway.
- 2.15 Part 2: notification processes for tobacco products
- 2.16 Proposed changes to current procedure:
- 2.17 Wherever a product is being sold in the UK, the Government will ask notifiers to upload the notification files to a secure government server. This is in addition to any requirements made by the TPD for notification in the EU. All notifiers will need to register with the UK portal to submit their data.
- 2.18 If a notifier uploads information on non-UK markets to the UK server, then this data will not be visible in the active UK system, but for the purposes of integrity the original data submitted will remain on our database.
- 2.19 If a notifier does not wish this information to be uploaded to the UK server, then they should remove that data before submitting to the UK.
- 2.20 Manufacturers who are unwilling or unable to submit information in the form set out above, will be required to complete an online form with all relevant data points, excluding points 38 to 56, listed in [TPD submission data dictionary – tobacco products v1.1.1](#). Any required attachments can be submitted along with the form. The form and attachments will be transferred using the same secure encrypted email function as is used to transfer all other data.

- 2.21 Part 3: changes to picture warnings
- 2.22 In the event of no deal, the UK will need to introduce new picture warnings for tobacco products as the copyright for the existing picture library is owned by the European Commission.
- 2.23 Manufacturers will need to ensure that tobacco products produced from exit day onwards feature new picture warnings, which have been secured by agreement with the Australian government.
- 2.24 Tobacco products featuring pictures from the EU library, produced before exit day, may be sold for 12 months after exit day.
- 2.25 There will be one set of pictures from exit day and therefore there will be no rotations between sets, as is currently the case (the EU picture library features 3 sets of 14 pictures, rotated on an annual basis).
- 2.26 The government intends to publish further guidance in relation to cropping and sizing of the images to ensure that the Australian images can be easily adapted by the industry and will conform to existing legislative requirements in relation to image and pack size.

3. Statistical Overview

Table 1: Breakdown of respondents

Respondents	Number of Responses
Large tobacco companies and representative bodies	4
Smaller tobacco/related companies/cigar companies/representative bodies	12
E-cigarette Interests	5
Tobacco Control interests	4
Retailers	1
Individuals	5
Other	1

There were 32 responses in total; not all respondents answered every question

Table 2: Number of responses for each question asked

Question	Number of responses
E-cigarettes: Can you inform us about any practical or technical issues that you think we should consider as part of the system that has been outlined above?	22
Tobacco products: Can you inform us about any practical or technical issues that you think we should consider as part of the system that has been outlined above?	23
Picture warnings: Can you inform us about any practical or technical issues that you think we should consider as part of the changes to picture warnings outlined above?	22
Picture warnings: Can you provide any information in relation to cost associated with changing the picture library?	21
Picture warnings: What further information would be helpful in terms of guidance to ensure that the transition to the new picture library is as smooth as possible?	22

4. Overview of Responses

Parts One and Two - Notification systems

Part One: notification processes for e-cigarettes

Part Two: notification processes for tobacco products

Can you inform us about any practical or technical issues that you think we should consider as part of the system that has been outlined above?

- 4.1 Strong support for the principle of aligning with the EU-CEG notification system: the extent of practical issues would depend on how far the UK's systems differed from the EU's for both e-cigarettes and tobacco products.
- 4.2 Concern raised by the industry around high IT and resubmission costs for e-cigarette and tobacco products.
- 4.3 Concern around data security and creating parallel submission systems for notification.
- 4.4 Question about how the UK will receive information about new submitter IDs issued by EU if the EU does not share them: can information from companies be trusted if they must submit the information themselves
- 4.5 Support for keeping the notification system as simple as possible with relevant guidance
- 4.6 Suggestion that the Government should design the system together with the industry.

Part Three - Picture Warnings

Can you inform us about any practical or technical issues that you think we should consider as part of the changes to picture warnings?

Can you provide any information in relation to cost associated with changing the picture library?

What further information would be helpful in terms of guidance to ensure that the transition to the new picture library is as smooth as possible?

- 4.7 Concerns from both representatives of big and small tobacco companies that the timescale for change is unrealistic given multi-national supply chains which cannot be changed to introduce new picture warnings with such a short transition period.
- 4.8 Concerns from the industry in relation to the substantial costs (in millions of pounds) associated with: artwork, tooling, time, and machinery.
- 4.9 Concern about the environmental impact of much wasted stock.
- 4.10 It was suggested that the UK Government should instead negotiate an agreement with the EU to continue to use the existing warnings.
- 4.11 The message in relation to picture warnings was not uniform. One smaller company commented that switching the pictures on packaging designs is a relatively 'easy' task. However, as health warnings rotate yearly, switching in May, rather than March, would reduce the practical challenges around the transition
- 4.12 Concern from the industry that disruption to UK supply chain could fuel illicit trade, with implications for public finances.
- 4.13 Tobacco control stakeholders supported the proposals as a short-term emergency fix. However, in the longer-term the Government should review the warnings (which are currently being evaluated by the Australian government) and find ways to increase the number to allow for rotation as is currently the case.
- 4.14 Several respondents called for realistic detailed guidance for cropping the Australian picture warnings on all types of tobacco and e-cigarette packaging
- 4.15 Concern was raised that there should be sufficient time for retailers to sell through non-compliant stock or have no specific sell by date at all.
- 4.16 Proposals for the picture warnings to be released 6 months before implementation with clear guidelines for portrait and landscape use of the pictures.

- 4.17 Specialist tobacco/cigar manufacturers argued that the changes could incur costs in the order of hundreds of thousands of pounds.

5. Next steps

- 5.1 It remains the Government's priority to secure a deal with the EU to ensure a smooth and orderly exit. The above changes will only come into effect if no deal is secured before the UK leaves the EU.
- 5.2 The Government remains firmly committed to reducing smoking after exiting the European Union. The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2019 have been made following Parliamentary debate to allow this to happen in a no deal scenario. These regulations will come into force on exit day.
- 5.3 DHSC has used the feedback from this consultation to inform accurate and relevant guidance on picture warnings and notification systems. It has shared the outputs with Medicines and Healthcare Products Regulatory Agency (MHRA) and Public Health England (PHE) to inform their IT development work so that any new notification systems are effective and efficient.
- 5.4 The Government notes that the industry concerns around cost and timing were not accompanied by substantial evidence or breakdown of costs. The Government recognises that the timescales are challenging but does not believe these are unreasonable. In relation to the timing issues highlighted in the consultation responses, there is no flexibility to amend this as the timeline needs to align with the timetable for EU Exit.
- 5.5 DHSC believe the issues raised in this consultation will be mitigated by the publication of detailed appropriate guidance. DHSC has provided further visual guidance to the industry in January 2019 to illustrate how the images and text of the combined health warnings should be presented on five example layouts. This is intended to mitigate the issues raised by the industry in the consultation, and ensure minimal burden on the industry.
- 5.6 Further guidance on new notification processes for new products, and changes to existing products will be published shortly by PHE and MHRA to help industry prepare to notify products in the event of a no deal scenario.