



Department
of Health

Government Response - Consultation on Regulatory Fees for Tobacco Products

Consultation on the Setting of Fees for Notification
and Testing of Tobacco Products

January 2017

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Executive summary

On 23 June 2016, 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.

On 25 October 2016, the Department of Health published a four-week consultation on proposals (a) to introduce proportionate fees for the notification of the placing on the UK Market of tobacco and herbal products for smoking; and (b) for the costs relating to the testing of cigarettes for levels of tar, nicotine and carbon monoxide (TNCO). These proposals relate to provisions of the Tobacco and Related Products Regulations 2016 which implement the Tobacco Products Directive 2014/40/EU (the Directive).

The Department received 47 responses. This document provides an overview of the responses received and a summary of the main themes that emerged in answer to the specific questions asked in the consultation document. It also sets out how the Government intends to proceed to make and lay the regulations in spring 2017.

The proposed fee structure is designed to cover the costs of Public Health England (PHE) (as the UK Competent Authority) incurred in receiving, storing, handling, analysing and publishing the information submitted by producers of tobacco products and herbal products for smoking cigarettes, and for the costs relating to testing cigarettes. The proposed fees are the minimum possible to ensure the costs incurred by PHE in undertaking these activities are recovered.

As a result of the consultation the proposed fees were lowered. The revised fees are set out below:

Notification of tobacco and herbal products for smoking:

| | | Service | | |
|------------------------|--|--------------|--------------|-----------------|
| | | Notification | Modification | Annual Periodic |
| Product type (grouped) | Cigarette, Roll Your Own (RYO), Novel Tobacco Products | £200 | £100 | £100 |
| | Other Tobacco Products (OTP) | £100 | £50 | £50 |
| | Herbal | £60 | £30 | £30 |

Verification of TNCO emissions in cigarettes

To recover the cost of verification of TNCO emissions in cigarettes, the fee is set at £1000 per product line.

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The Government Regulatory Triage Assessment, issued with the consultation document, has been updated and finalised taking account of information and evidence received in response to the consultation. A Validation Impact Assessment is published alongside the Regulations.

1. Background to the Consultation

The Government consulted from 2 July to 3 September 2015 on the implementation of the Tobacco Products Directive 2014/40/EUⁱ including whether to recover from industry the costs of certain functions assigned to Member States by the Directive. In the Government responseⁱⁱ the Government indicated that it would take powers to charge fees for:

- Verification of tar, nicotine and carbon monoxide (TNCO) in cigarettes;
- Notification of tobacco products - the receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products (inc. novel tobacco products);
- Notification of e-cigarettes - the receiving, storing and handling and analysing of information submitted on e-cigarettes;
- Assessing whether a tobacco product has a characterising flavour; and
- The peer review of scientific studies on additives (on the European Union priority list of additives) undertaken by the tobacco industry.

In January 2016 the MHRA launched a public consultation on fees levels for e-cigarette notificationⁱⁱⁱ and regulations to charge the industry were made and came into force in May 2016^{iv}.

Since the consultation on implementation of the Tobacco Products Directive and subsequent Government response, the Commission has published further Implementing Acts on the assessment of characterising flavours^v and the priority list for additives^{vi}. These set out how these procedures will operate and be co-ordinated at EU level. Indications are that much of the analysis and evaluation will be undertaken at EU level and the impact and therefore any associated costs to Member States remains uncertain. The Government is minded not to take forward legislation to impose fees in these areas at this time.

The consultation outlined proposals to set fees for the remaining areas, namely, for the costs relating to notification and submission of data on tobacco products and herbal products for smoking, and for the costs relating to the testing of cigarettes for tar, nicotine and carbon monoxide. A list of questions included in the consultation is provided at [Annex A](#).

The consultation '*Fees proposals: tobacco and herbal products for smoking*' is published on www.gov.uk.

2. Overview of responses

Number of responses received

The Department of Health received 47 responses to this consultation. The largest group of respondents were members of the public (23) and the tobacco industry - manufacturers, importers, specialist tobacco retailers and trade associations (23). The remaining response was received from the public health charity Action on Smoking and Health (ASH).

Of the 47 responses:

- 41 respondents (87%) were against the proposed level of fees
- 4 respondents (9%) agreed with the proposed level of fees
- 2 respondents (4%) did not know/did not answer.

A list of all respondents, less members of the public is provided at [Annex B](#).

Main themes

Levels of charging

The level of the proposed fees was raised by some respondents. Some consultation responses suggested that the fees should be similar to those charged by the MHRA to cover regulatory activity relating to notification of electric cigarettes. The MHRA fees are £150 for an Initial Notification (£90-£220 proposed for tobacco products), £80 for Modification (£45-£110 proposed for tobacco products) and a £60 for an Annual (Periodic) fee (£45-£110 proposed for tobacco products).

Government Response

The proposed fees are at levels consistent with those charged to e-cigarette businesses for similar activities. The tobacco system covers a smaller number of notifications and has different fixed and variable costs associated with the provision of the service. The Government is committed to review fee levels to ensure that they recover costs and generate neither a surplus nor deficit.

The proposed fees for tobacco products compare favourably with that charged by other Member States. From the information currently available of the Member States that have confirmed that they are charging the tobacco industry to recover costs, notification fees range from €125-€5,000, with higher fees charged for notification of novel tobacco products and testing of cigarettes. The proposed fees in the UK are therefore at the lower end of the fees charged across the EU.

Fewer Brand variants

Some respondents suggested that there may be fewer new brands in the future with the introduction of a range of new legislation: a point of sale display ban, standardised packaging laws, and the new product standards under the Tobacco and Related Products Regulations 2016, including a ban on flavours from May 2016 (with the transition period for the ban on products with menthol flavour ending in 2020). Some consultation responses highlighted that they are actively reducing their product ranges to comply with the new regulatory requirements.

Government Response

Reduction of product ranges is already factored into our estimates, as is the potential increase in novel tobacco products. The Government is committed to regularly review fee levels to ensure that only costs incurred are recovered, without accruing a surplus or deficit.

Estimates on the number of cigarettes submitted for testing

Respondents provided little information to refine the estimates for the number of cigarettes submitted for testing. Respondents did make observations that the introduction of the Tobacco and Related Products Regulations 2016 may cause some fluctuations in the number of cigarettes placed on the market and therefore tested.

Government Response

The proposed estimates take account of the estimated likely variation. The Government is committed to regularly review fee levels to ensure that only costs incurred are recovered, without accruing a surplus or deficit.

Estimated number of modifications

Some respondents reflected that it is very difficult to estimate how many modifications might take place as the market adjusted to the Tobacco and Related Products Regulations 2016 and other regulatory changes. Respondents consider the proposed estimate of 35 modifications is a substantial underestimate at least in the near future. Estimates provided range from zero to 67 modifications per company.

Government Response

The central estimate on the number of modifications in the Government's supporting analysis has been increased as a result of this further information. Further details are provided in the accompanying Validation Impact Assessment. The Government is committed to regularly review fee levels to ensure that only costs incurred are recovered, without accruing a surplus or deficit.

Assessment of impact on UK based activity

Consultation responses provided no information on the proportion of UK-based activity. Some businesses questioned the methodology used in the Regulatory Triage Assessment to assess costs accrued by UK based businesses.

Government Response

No further information was received. A "GDP-based approach" is adopted to estimate the UK proportion of total costs to business. This approach requires an assessment of the proportion of value-added activity that occurs in the UK, and is generally referred to as UK-based activity. Other more general comments around the 'Other Tobacco Products' (OTP) sector (e.g. generally wide product ranges sold in low volumes) made us reconsider our estimates. We conclude that the most appropriate estimate to use for proportion of UK-based activity for OTP is 100%. This is higher than the 5.8% used in the RTA. The same estimate is applied to herbal products for smoking. Further details are provided in the accompanying Validation Impact Assessment - see "Annex B – UK Proportion".

Alternative methods of cost recovery

Two respondents expressed the view that the recovery of costs as outlined at consultation, are too complex and costly to administer. They suggest a more efficient model would be to recover the costs of notification of tobacco products and testing of cigarettes via existing tax receipts, which amount to over £9billion.

Government Response

The fees proposed recover PHE's costs in providing a service to the industry in processing notifications and testing cigarette emissions. The fee structure is set to ensure that relevant businesses are charged for the services that they use and that there is no cross subsidy from one sector to another or from those businesses not subject to tobacco duty to those that are not.

Sector-specific

Snuff industry

Snuff is a form of smokeless tobacco product inhaled via the nasal cavity. Products consist of ground or pulverised tobacco leaves and are available in wide variety of flavours.

A number of respondents suggested that the estimates of the number of snuff products expected to be notified were too low and called for snuff to be exempt from fees, as these products are artisan and produced largely by small businesses. Very few responses provided any estimates of the number of snuff products currently on the market or expected to be notified under the legislation. Only two respondents provided their opinion, estimating 300 for the whole industry and 1000 different snuff varieties for one company.

Government Response

Under the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (the 2002 Regulations), which were revoked and replaced by the Tobacco and Related Products Regulations 2016, producers of snuff products were already legally required to notify the Department of Health of their product's ingredients and information on the toxicity and addictive effects of those ingredients (Regulation 12 of the 2002 Regulations). Only 11 snuff products were registered under the previous legislation.

The estimate of over 1000 products far exceeds the number of products registered under the 2002 Regulations and the 87 products registered on the EU Common Entry Gate (EU CEG) under the TRPR, which required all tobacco products placed on the market as of 20 May 2016 to be notified to the UK competent authority (Public Health England) by 19 November 2016.

There may therefore be many snuff product lines being sold that have not been registered, under either the 2002 Regulations or the new Tobacco and Related Products Regulations 2016. To reflect this information the central estimates in our analysis and the accompanying Validation Impact Assessment have been increased and the uncertainty estimates widened. See accompanying Validation Impact Assessment for further details.

Pipe tobacco

Respondents provided limited information concerning estimates and proposed fees for pipe tobacco. One respondent raised similar concerns to that of the snuff sector, in that the pipe tobacco sector consists of a large range of low volume products. The majority of respondents

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who provided information referred to estimates provided by the Imported Tobacco Products Advisory Council (ITPAC), which estimates 320 pipe tobacco products on the UK market.

Government Response

The information received suggests the proposed estimates at consultation stage are reasonable. To take account of the wider uncertainty on estimates for the 'Other Tobacco Products' category, the higher and lower sensitivity estimates have been widened. Further details are provided in the accompanying Validation Impact Assessment.

Cigars

Again limited information was provided for cigars. The majority of respondents who provided information referred to estimates provided by Imported Tobacco Products Advisory Council (ITPAC), which estimates there are around 900 cigar products currently on the UK market.

Government Response

The information received suggests the proposed estimates at consultation stage are reasonable. To take account of the wider uncertainty on estimates for the 'Other Tobacco Products' category, the higher and lower sensitivity estimates have been widened. Further details are provided in the accompanying Validation Impact Assessment.

Herbal product for smoking

No further information was provided in relation to herbal products for smoking.

Government Response

No further information was received. The final fee structure is based on the estimates used at consultation stage.

3. Fees for Notification of Tobacco Products and Herbal Products for Smoking

In accordance with the revised EU Tobacco Products Directive Tobacco Products Directive 2014/40/EU PHE will manage an electronic notification system for tobacco and herbal products intended for the UK market. Fees have been set to recover the costs of PHE providing these services.

Proposed fees at consultation

Pre-consultation, the proposed fees, to recover PHE costs, had been set at:

| | | Service | | |
|------------------------|--|--------------|--------------|-----------------|
| | | Notification | Modification | Annual Periodic |
| Product type (grouped) | Cigarette, Roll Your Own (RYO), Novel Tobacco Products | £220 | £110 | £110 |
| | Other Tobacco Products (OTP) | £135 | £65 | £65 |
| | Herbal | £90 | £45 | £45 |

Revised fees

Using the new volume estimates adjusted to take into account consultation responses and particularly acknowledging the uncertainty in the Other Tobacco Products sector, the fees have been revised downwards as follows:

| | | Service | | |
|------------------------|--|--------------|--------------|-----------------|
| | | Notification | Modification | Annual Periodic |
| Product type (grouped) | Cigarette, Roll Your Own (RYO), Novel Tobacco Products | £200 | £100 | £100 |
| | Other Tobacco Products (OTP) | £100 | £50 | £50 |
| | Herbal | £60 | £30 | £30 |

4. Fees related to the Testing of Cigarettes for Tar, Nicotine and Carbon Monoxide

The Government also intends to introduce fees for the testing of cigarettes for tar, nicotine and carbon monoxide. PHE will take over this responsibility, which is a continuation of current activity undertaken by the Department of Health. Fees are set to recover costs associated with the performance by the Secretary of State of the functions conferred on him in regulation 14(3) of the Tobacco and Related Products Regulations 2016, and the verification of the measurements by laboratories under regulation 14(3)(b) of the 2016 Regulations. PHE will incur costs in tendering and managing the testing contract, in liaising with the tobacco industry, and for the analysis of the tobacco products.

Proposed fees at consultation

To recover the cost of verification of TNCO emissions in cigarettes, the Government proposed at consultation stage to introduce a fee per product line of £1200. This figure is based on the costs of the current testing contract and management costs.

Revised fees

Based on the volume estimates provided in response to the consultation, the fees have been revised downwards to £1000 per product line.

5. Next steps

The Department of Health thanks all respondents for their contributions and intends to proceed with legislation to introduce the new fees. The Government will shortly make and lay before Parliament regulations imposing fees relating to the notification of tobacco products and herbal products for smoking and testing of cigarettes. The intention is that the new legislation will come into force on 6 April 2017.

Public Health England will seek to issue guidance and work with all producers to ensure they understand the charging regime and mechanism for collection of the appropriate fee.

Fees will be first payable -

| | |
|-------------------------------|---|
| Testing of cigarettes | on 1 March 2018, and thereafter each year on 1st March |
| New Notification/Modification | at the time the information is submitted, commencing for notifications submitted after 6 April 2017 |
| Annual notification fee | on 1 March 2018 thereafter each year on 1st March |

Review

Due to the uncertainties in the volumes of notifications and products submitted for testing, the volumes of products received in the first year of operation and costs will be reviewed, and upward or downward adjustments made as necessary to the fees to ensure these remain proportionate and neither under or over-recover costs.

The policy of charging will be reviewed alongside the main UK Tobacco and Related Products Regulations 2016 within 5 years.

Annex A

List of consultation questions

1. Do you have any information that would help the Department to refine its estimates on the numbers of tobacco and/or herbal products that will be notified under the Tobacco Products Directive?
2. Do you have any information that would help the Department to refine its estimate on the number of cigarette products that will be submitted for testing each year?
3. Do you have any information that would help the Department to refine its estimate on the number of modifications that will be made to product information each year?
4. Do you have any information that would help the Department to refine the sector-specific (i.e. cigarettes, hand rolling tobacco etc.) estimates of the proportion of the costs incurred by business in the UK?
5. Do you agree or disagree that the levels of the proposed fees are proportionate? If you disagree, please explain why.

Annex B

List of respondents: Companies and organisations

Action on Smoking and Health (ASH)

Association of Independent Tobacco Specialists (AITS)

Black Swan Shoppe Ltd

British American Tobacco

Choice Select

Davidoff Distribution (UK) Ltd

Duckworths

Eaglecloud II Ltd t/a "Lorforde"

Farrants

Gawith Hoggarth & Co Ltd

Havana House Ltd Oxford

Havana House Ltd Windsor

Hunters & Frankau Ltd

Imperial Brands

ITPAC

J J News

Japan Tobacco International

Karelia Tobacco Company INC

Mysmokingshop Ltd

Scandinavian Tobacco Group UK Ltd

Tabac World Ltd

The Pipe Shop Wessex Ltd

Toque Snuff Ltd

Tor Imports Ltd

ⁱ <https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products>

ⁱⁱ <https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products>

ⁱⁱⁱ <https://www.gov.uk/government/consultations/regulatory-fees-for-e-cigarettes>

^{iv} The Electronic Cigarettes etc. (Fees) Regulations 2016 <http://www.legislation.gov.uk/ukSI/2016/521/made>

^v Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour

^{vi} Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations (notified under document C(2016) (2923))