Department of Health

# Consultation on Regulatory Fees for Tobacco Products

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

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# Consultation on Regulatory Fees for Tobacco Products

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

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# Purpose of this Consultation

The aim of this consultation is to seek the views on proposals to introduce proportionate fees for the notification of the placing on the UK Market of tobacco and herbal products for smoking and for the testing of cigarettes for levels of tar, nicotine and carbon monoxide under the provisions of the Tobacco and Related Products Regulations 2016 which implement the Tobacco Products Directive 2014/40/EU. A regulatory triage assessment is published alongside this consultation and sets out the methodology and assumptions the Department has made in developing this proposal.

This proposal seeks to introduce new fees for manufacturers and importers of tobacco and herbal products in order for Public Health England (PHE) (as the UK Competent Authority) to cover the costs of processing notifications and for testing cigarettes. The proposed fees will be the minimum possible to ensure the costs incurred by PHE in undertaking these activities are recovered.

We propose implementing these fees in 2017.

The proposed fees may be reviewed should data obtained during consultation enable the further refining of cost estimates.

# Background to the Consultation

## Government Consultation on the Implementation of the Tobacco Products Directive 2014/40/EU

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, including the revised Tobacco Products Directive. It will be for the Government to begin negotiations to exit the EU. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation and funding in future once the UK has left the EU.

The Government consulted, from 2 July to 3 September 2015 on the implementation of the Tobacco Products Directive 2014/40/EU[i] including whether to recover from industry the costs of certain functions assigned to MS by the Directive. In the Government response[ii] 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;
- Notification of e-cigarettes - the receiving, storing and handling and analysing information submitted to them on e-cigarettes;
- Assessing whether a tobacco product has a characterising flavour; and
- The peer review of scientific studies on additives undertaken by the tobacco industry.

In January 2016 the MHRA launched a public consultation on fees levels for e-cigarette notification and laid regulations to charge industry from May 2016.

Since the consultation on implementation and the Government response the Commission has published further Implementing Acts on the assessment of characterising flavours and the priority list for additives[iii]. These set out how these procedures will operate and the Government is minded not to take forward legislation to impose fees in these areas at this time.

This consultation sets out proposals to set fees for the remaining areas of notification and testing of cigarettes for tar, nicotine and carbon monoxide.

# Proposals for Charging Fees

## Notification of Tobacco Products

In accordance with the revised EU Tobacco Products Directive (TPD), PHE will manage an electronic notification system for tobacco and herbal products intended for the UK market. The notification system will be connected to an EU Portal and PHE will need to make adequate checks of those notifications and annual sales and marketing reports relating to products for the UK market to ensure that they are correct, complete and compliant and respond to enquiries from producers, enforcement, Member States (MS), the Commission and consumers about the data.

PHE will also be responsible for collating and publishing a public facing data set for products on the UK market taking into account the need to protect commercially sensitive and personal data submitted as part of the notification. These data will be freely available, including to industry, consumers, enforcement officers and academics.

Total costs, inclusive of fixed cost overheads, are estimated to be approximately £129,901 per year. To deliver and maintain the notification system, staff across a number of areas within PHE will be required in addition to the IT:

- Information Processing and Advice - Staff to advise businesses on completion of the form and to review submitted notifications and assess the correctness of data within the categories which will be monitored by PHE. Estimates of numbers of staff required are based on the time to complete a notification and the estimated volume of notifications.
- Finance – Staff will be required to raise invoices and follow up on unpaid invoices. Submission is likely to be received from companies based in locations worldwide, providing an added degree of complexity to chasing debt.
- Toxicological Advice – Staff will be required to assess the scientific data submitted via the notification system.
- IT/Communications – Staff will be required to either generate the publication of the notifications manually or check and monitor that any system generated publication has produced the correct results. Information relating to the notification will need to be published and staff will be required to check that this has occurred correctly and (for example) any commercially sensitive documents have not been published.
- Process Manager – A manager responsible for ensuring that the end to end process, from receipt of information from the portal to publication of information on the notifying organisation, has occurred correctly.

Staffing numbers are dependent on the number of notifications received. Our proposals are based on market data and the level of current notifications that the Department of Health has received under the existing legislation (The Tobacco Products (Manufacture, Presentation and Sale)(Safety) Regulations 2002. We estimate the following number products on the UK market and the number of modifications and introductions as follows:

## Table 1 – Estimated number of notifications by product type (grouped)

| Product type (grouped) | Estimated number of product lines subject to annual periodic fee | | | Estimated number of product lines that will notify | Estimated number of product lines for which modifications will be made |
|---|---|---|---|---|---|
| | Central | Low | High | | |
| Cigarettes, Roll Your Own and Novel Tobacco | 206 | 194 | 218 | 35 | 35 |
| Other Tobacco Products | 1,379 | 1,012 | 1,745 | 60 | 0 |
| Herbal products | 30 | - | - | 3 | 3 |
| Estimated total | 1,615 | 1,236 | 1,993 | | |

Around 35 modifications to cigarette notifications are currently made per year. These include:

- Changes to the declaration on emissions
- Brand name changes
- Butt length changes
- Changes to the declaration on the amount of ingredients or type of ingredients used

DH also receives approximately 35 new cigarette product notifications a year for new introductions to the market.

Data from industry representatives indicates around 60 new other tobacco products enter the market every year.

In calculating the proposed fees we have taken into account that the ban on flavours to be introduced for cigarettes and hand rolling tobacco by the Tobacco and Related Products Regulations 2016 from May 2016 will reduce the numbers of product on the market. In addition, we anticipate the final stage of the display ban which came into force for small retail outlets from October 2015 and new regulations on standardised packaging and the labelling requirements of the TPD will also impact on the levels of new products being developed and entering the market and also that the numbers of products that are currently offered will reduce.

The initial financial modelling to determine the fees shown in this consultation were based on these data and assumptions.

To recover the cost of the scheme, the Government proposes to introduce the following notification fees:

## Table 2 - Proposed fee structure (£) for notifications.

| | | 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 |

It is our intention to charge the initial notification fee and modification fee for all products introduced or modified after the fees regulations come into force. We anticipate this will be in 2017. All products on the database will be liable for the annual periodic fee.

These figures have been set in order to recover only the estimated costs and could be revised based on any further evidence from this consultation. In all cases adjustments to fees will be set at the minimum possible to safely recover the cost of providing the ongoing service.

## 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. This is a continuation of current activity undertaken by the Department of Health which is contracted out to an accredited laboratory independent of the tobacco industry.

In addition to the cost of testing the product, DH will incur costs in tendering and managing the testing contract and liaising with the tobacco industry. These include:

- Finance – Staff will be required to raise invoices and follow up on unpaid invoices. Businesses submitting samples for testing are likely to be based in locations worldwide, providing an added degree of complexity to chasing debt.
- Contract Manager and Procurement Expertise – staff responsible tendering, awarding and managing the contract for testing cigarettes. Managing the contract will include:
- taking action to ensure samples are submitted to the laboratory
- quarterly monitoring of the key performance indicators and annual visit to ensure quality standards and the deliverables set out in the contract with the laboratory
- receiving and quality assuring bimonthly and annual reports from the laboratory
- taking action to notify tobacco companies of the results including, any breaches of the legal limits for tar, nicotine and carbon monoxide as determined by the laboratory
- Financial control over the contract and liaison with DH Finance on invoicing and recovery of fees from the tobacco industry.
- Toxicological advice – as necessary to advise on the results of testing and their significance

All cigarette manufacturers are currently required to submit samples of their product for testing 6 times a year. To recover the cost of testing cigarettes, the Government proposes to introduce a fee per product line of £1200. This figure is based on the costs of the current testing contract and the above management costs, as with all fees and charges, will be subject to annual review. The fees set out do not cover any costs associated with enforcement action taken for breaching the legislative limits.

# 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.

# How to get involved in the consultation

The consultation questions set out in this summary section of this document. The consultation will run for 4 weeks, **from 25 October 2016 to 22 November 2015.** We welcome responses from any interested person, business or organisation.

Respondents can provide their views online by completing our online survey via our dedicated consultation portal at **https://consultations.dh.gov.uk/tobacco/regulatory-fees-for-tobacco-products-2.**

The purpose of this consultation is to seek the views of interested people, businesses and organisations, on proposed fees for the notification of tobacco products and the testing of cigarettes for tar, nicotine and carbon monoxide.

We ask that you provide references to data or other evidence with your responses.

If you wish to get a copy of this consultation document in an alternative format, or need to respond in an alternative format for accessibility reasons, please contact us using the email or postal addresses given below in the section titled 'Consultation process'**.**

The Department of Health will not be able to respond to individual consultation responses.

## Declaration of direct or indirect links to the tobacco industry by respondents

As a Party to the World Health Organisation's Framework Convention on Tobacco Control (FCTC), the United Kingdom has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To meet this obligation, we ask all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. We will still carefully consider all consultation responses from the tobacco industry and from those with links to the tobacco industry and include them in the published summary of consultation responses.

## Next steps

All responses received by **23:59 on 22 November 2016** will be carefully considered. A summary report of consultation responses will be published on the Department of Health website in due course, once the consultation has been completed.

The draft regulations will be finalised, taking into account all relevant considerations.

## Consultation process

If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please contact:

Consultations Coordinator

Department of Health

2E26, Quarry House

Leeds

LS2 7UE

Email: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

## Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that under the FOIA there is a statutory Code of Practice with which public authorities must comply, dealing with obligations of confidentiality. In view of this, it would be helpful if you could clearly identify any confidential information in your response and explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that it will not be disclosed to third parties.

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***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 http://www.legislation.gov.uk/uksi/2016/507/resources***