

Regulatory Triage Assessment – Department of Health

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Title of proposal	Fees for TNCO testing of cigarettes and notification of tobacco and herbal products under the Tobacco Products Directive (TPD) – Consultation Stage
Expected date of implementation	January 2017
Origin (Domestic/International etc.)	International (EU)
Date	18/5/16
Lead Policy Contact	Alette Addison
Lead Analytical Contact	Nadia Yegorova-Johnstone
Reason for Triage Assessment	Cost to business is under £1m a year
Is the policy in scope of OI3O?	No, the policy is considered out of scope as it implements an EU Directive.
<p>Please provide a brief description of the policy proposal</p> <p>The Department of Health (DH) is proposing to charge the tobacco industry fees from January 2017 to fully recover costs associated with the following functions assigned to Member States by the Tobacco Products Directive 2014/40/EU (TPD2):</p> <ol style="list-style-type: none"> <u>The testing of cigarettes for tar, nicotine and carbon monoxide (TNCO)</u> DH currently incurs costs for procuring and managing a contract with Essentra, and for the analysis that the Essentra laboratory undertakes for TNCO levels in cigarettes according to defined ISO standards¹. DH also incurs costs for liaising with cigarette manufacturers and importers and supplying them with test result data assuring that their product remains compliant with the legislation. It is DH's intention to charge an annual fee per product line (on the market) to recover the costs of this service. <u>The notification of tobacco and herbal products</u> DH proposes to set fees to recover the costs associated with receiving, verifying, analysing and publishing data on tobacco and herbal products. This includes emissions and ingredients data, as well as sales and market survey data. <p>The principle of charging industry proportionate fees to recover costs is an optional extension to the transposition of TPD2 and was openly consulted on without preference by the UK Government. DH has commissioned Public Health England (PHE) to carry out these activities. Fees must be set in line with Managing Public Money principles, which stipulate that the Government should neither profit at the expense of industry, nor make a loss for taxpayers to subsidise. Fees will be revised in Year 2 in the event of a surplus or deficit.</p>	
<p>How many businesses are likely to be affected? <i>(This includes private business, third sector and Universities)</i></p> <p>All manufacturers and importers in the UK market for tobacco and herbal products (including novel tobacco products) will be affected in relation to the number of products they intend to submit for testing or notify. DH data suggests that approximately 10 companies submit products for testing each year and approximately 20-30 companies notify products each year.</p>	
<p>What are the main impacts for business? Are these impacts direct or indirect?</p> <p><u>Direct impacts:</u></p> <ol style="list-style-type: none"> For testing, businesses will incur a per product line cost on an annual basis. For notification, businesses will incur a one-off notification cost for each product line. They will also incur a modification fee each time there is a modification to the initial notification. They will 	

¹ International Organisation for Standardisation (ISO) sets and promotes international standards on tobacco and tobacco products.

also incur an annual periodic fee per product line.

Indirect impacts: Manufacturers and importers that are unable to afford these fees will either have to adapt their business models or withdraw from the legal market. This is likely to have an indirect effect on retail businesses selling their products. This impact is likely to be larger for small businesses that sell a wide variety of low-volume SKUs, particularly in the cigar and pipe industries.

Please provide a quantification of the (direct) costs and benefits to business outlined above:

Total costs to business: £308,000 (of which **£25,000** UK-based). Costs to business are estimated as the income received by Government from fee payments. All costs refer to those incurred in Year 1 (financial year 17/18) and are provided to the nearest thousand. All fees are set to recover full economic costs, which includes a 3.5% cost of capital. See Annex A (1) and (2) for the full methodology. See Annex B for the method used to calculate the UK proportion of impact.

1. Total testing fee payments in Year 1: £174,000 (of which **£14,000** UK-based)

DH proposes a set annual fee per product line subjected to testing of £1,200. This fee is calculated by dividing the estimated costs of testing to Government by the estimated number of product lines on the market in 2017/18 that will be subjected to testing. See Annex A (1) for more detail.

2. Total notification fee payments in Year 1: £134,000 (of which **£11,000** UK-based)

DH proposes a fee structure that differentiates fee levels depending on the service and the type of product (see Table 1 below). The differentiation of fees is based on the number of required data fields (and hence the relative workload) for each service and product (see Table 5 in Annex A (2) for more information). Fee levels are set such that the total Government income from fees covers the total cost of notification incurred by Government for providing the service in 2017/18, which is estimated at £130,000. See Annex A (2) for more detail.

RISKS: There is a substantial risk of a surplus or deficit due to uncertainty surrounding the estimated number of fee payments. This uncertainty is reflected in the plausible range for estimated income from both cost recovery schemes: £264,000-£350,000, which remains well below the £1m threshold. We aim to address the main evidence gaps through the Consultation (see Annex C for more information).

Table 1- 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

Total Benefits to Business: £0

There are no perceived benefits to business of charging regimes for testing or notification. Charging industry represents a transfer of costs from taxpayers to business.

Please provide details of other costs and benefits that are likely to result from the policy:

Costs: Costs may also be passed onto consumers if businesses increase prices of products to cover their own costs. However, these costs are likely to be small and could be offset by the health benefits accruing to consumers that reduce their consumption of cigarettes due to the higher prices.

Benefits: As the tobacco industry partially consists of large multi-national companies, this would represent a shift in the cost of EU TPD testing and notification activities from the UK Government (and hence, the taxpayer) to firms that are only partly UK-based.

Policy signoff (SCS):

Date:

Senior Analyst signoff: Rob Unsworth

Date: 18/05/2016

Better Regulation Unit signoff:

Date: 14/06/2016

Annex A - Fee setting methodology

1. The testing of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes

(a) Estimation of total costs incurred by Government:

Total costs of this service in the financial year 2017/18 are estimated at **£173,000**. We have used costs from the current service to inform estimates:

- DH has contracted Essentra – an analysis laboratory – to undertake the testing work on behalf of DH. This contract was extended in December 2015 by a further two years (to December 2017) at a cost of £266,000. This is divided by two to produce an estimated annual cost of £133,000.
- DH incurs staffing costs associated with the procurement and management of the contract and liaison with the tobacco manufacturers and importers. The current allocation of resource to the testing function in DH is used to inform the full time staff equivalent assumptions. There is uncertainty in whether these assumptions would remain accurate when this function is transferred to PHE. Table 2 includes a range of +/- 25% in FTE assumptions in square brackets to analyse the impact of this uncertainty on costs.
- FTE assumptions are multiplied by average London PHE salaries to estimate staffing salary costs in 2017/18. Annual staff cost comprises the basic salary plus national insurance and superannuation (pension) payments. The resulting range in staff costs is included in square brackets in Table 2.
- Table 3 summarises the central cost estimate for testing in 2017/18, with the credible range in square brackets. The total cost comprises the analysis contract, staff salary costs and overheads. The latter represent the infrastructure cost associated with testing and is calculated using the PHE rate of 50% of staff costs.

Table 2 – Staff salary costs (with sensitivity analyses in square brackets) in 2017/18

Employee Grade	Full Time Equivalent (FTE) [+/- 25%]	Annual Staff Cost (2017/18)
HEO	0.3 [0.225 – 0.375]	£11,193 [£8,395 – £13,991]
Grade 7	0.2 [0.15 – 0.25]	£12,960 [£9,720 – £16,200]
Grade 5	0.02 [0.015 – 0.025]	£2,416 [£1,812 – £3,020]
Total staff salary costs		£26,569 [£19,927 – £33,211]

Table 3 – Testing cost estimate 2017/18

Analysis Contract	£133,000
Staff Salary Costs	£26,569 [£19,927 - £33,211]
Staff Cost Overhead	£13,285 [£9,964 - £16,606]
Total costs	£172,854 [£162,891 - £182,817]
Total costs (to 3 significant figures)	£173,000 [£163,000 - £183,000]

(b) Estimation of products subjected to testing:

Testing is virtually a continuous process, with product lines submitted bimonthly (roughly 6 times as year) to meet international standards. The number of product lines that will be subjected to testing in 2017/18 is estimated at **145**. This estimate considers the 160 cigarette product lines on the market in 2016, less the 15 cigarette product lines that are expected to be removed from the market from May 2016 onwards (following the ban on flavours in cigarettes and roll your own tobacco under the Tobacco and Related Products Regulations 2016). There is considerable uncertainty around this estimate and we aim to collect more information on this through the Consultation (see Annex C for more information). The analysis includes a credible range in the estimated number of product lines (131-160), calculated as +/-10% of the central estimate, 145. This is included in Table 4.

(c) Estimation of per product line fee:

The proposed fee per product line is **£1,200**. Using central estimates, this is calculated by dividing the total cost by the number of product lines subjected to testing in 2017/18. The fee is rounded to the nearest £100. Table 4 provides a summary of this calculation, including the credible range in number of product lines submitted (+/- 10% of the central estimate) and in the total cost incurred by the Government (+/-50% of central FTE estimates set out in Table 2). The sensitivities are reflected in the credible range of the per product line fee, providing an indication of the potential revision of fees in Year 2.

This is estimated to bring in an income of **£174,000**, the central estimate in the range of £157,000 to £192,000 (due to the credible range of testing fee payments). Note that the slight discrepancy between the estimated costs to Gov't and income received by Gov't is due to rounding the annual fee to an appropriate £100 of precision. A surplus or deficit of less than 5% of total costs is considered breakeven, to allow for a margin of error of cost recovery.

Table 4 – Summary of fee calculation (including sensitivity analyses in square brackets)

Number of testing fee payments	Total cost incurred by Gov't	Fee per product line (rounded to nearest £100)
145	£173,000	£1,200

[131 – 160]	[£163,000 - £183,000]	[£1,000 - £1,500]
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2. The receiving, storage, handling, analysis and publishing information on ingredients and emissions of Tobacco and Herbal products

(a) Overview of requirements:

Manufacturers, retailers and importers in the UK market for tobacco and herbal products will be subject to fees when submitting the required information on each product line. DH proposes to differentiate fees to cover costs associated with servicing different activities:

- Businesses must submit an **initial notification** of the required data for each product line so that those products can be legally traded on the UK market. For products already on the market, notifications must be submitted between May 20th and November 19th 2016. DH will only recover costs for new notifications from January 2017 onwards. For all notifications submitted from 1st January, DH proposes a corresponding **initial notification fee**.
- Businesses must also notify any **modifications** of the required data as and when recipes change or more up-to-date data becomes available. For this, DH proposes a corresponding **modification fee**.
- **Ongoing activity** includes receiving data that is required annually and hosting, analysing and publishing the data. For this, DH proposes a corresponding **annual periodic fee per product line**.

(b) Estimated costs of PHE notification service to Government:

We have estimated the total cost of the PHE notification service at **£130,000** per year, using assumptions about required staff time from DH experience and PHE figures for salary and Information Technology (IT) costs. The annual salary covers the basic salary plus national insurance and superannuation (pension payments). Overheads are included in the total cost as 50% of total staff costs (PHE rate). See Table 5 for more information.

As in the costing for testing, the full time staff equivalent assumptions are based on the current allocation of resource to the notification function in DH. There is uncertainty in whether these assumptions would remain accurate when this function is transferred to PHE. Table 5 includes a range of +/- 25% in FTE assumptions in square brackets to analyse the impact of this uncertainty on costs. The resulting range in staff and total costs is included in square brackets in Tables 5 and 6.

Table 5 – Estimated staff salary costs (with sensitivity analyses in square brackets)

Employee Type	Full Time Equivalent (FTE)	Annual Cost
HEO	1 [0.75 – 1.25]	£37,311 [£27,983 - £46,639]
HEO Finance Role	0.1 [0.075 – 0.125]	£3,731 [£2,798- £4,664]
G7	0.3 [0.225 - 0.375]	£19,440 [£14,580 - £24,300]
G7 Finance Role	0.02 [0.015 – 0.025]	£1,296 [£972 - £1,620]
G6 Toxicological Support	0.2 [0.15 – 0.25]	£16,379 [£12,284 - £20,474]
Total staff salary costs		£78,157 [£58,617– £97,697]

Table 6 – Estimated total cost of PHE notification service to Government in 2017/18 (with sensitivity analysis in square brackets)

IT costs	£12,667
Staff Salary Costs	£78,157 [£58,617 – £97,697]
Staff Cost Overhead	£39,079 [£29,309 - £48,849]
Total costs	£129,901 [£87,926 - £146,546]
Total costs to 3 significant figures	£130,000 [£87,900 - £147,000]

(c) Setting of fees:

DH proposes a fee structure for total cost recovery in which fees are differentiated to reflect the associated cost of each activity. In the absence of the information required to distinguish between fixed costs and the variable costs, and also between the variable costs of each activity, we use an iterative approach to set fees based on assumptions about the relative workload of each activity. Fees will be set such that the total income from the fee structure recovers total cost to Government.

The following method was used to determine the relative workload and hence the relative cost of each activity, using knowledge gained through current notification activity carried out by DH. Refer to Table 7 for each step of the method (paragraph numbers are referenced in the table).

- i. Consider that the cost per initial notification for cigarettes, roll your own and novel tobacco is an amount x .
- ii. It is assumed that the cost per initial notification for other tobacco products is lower than for cigarettes, roll your own and novel tobacco given that notification of products in the latter group is more detailed (more data fields) and requires toxicological expertise for the reviewing of the submitted information. Therefore, **the cost per initial notification for other tobacco products is assumed to be 60% of that for cigarettes, roll your own and novel tobacco (represented as $0.6x$)** which makes it greater than half but still substantially lower than the cost per initial notification for cigarettes, roll your own and novel tobacco.
- iii. It is assumed that the cost per initial notification for herbal products is less than that for the two other product groups, due to the smaller number of data fields required. Therefore, the **cost per initial notification for herbal products is assumed to be 40% of that for cigarettes, roll your own and novel tobacco (represented as $0.4x$)** which makes it greater than half but still substantially lower than the cost per initial notification for other tobacco products.
- iv. It is assumed that the cost per initial notification is higher than the cost per modification and annual periodic cost per product line across all product groups. This is because modifications will only involve a few data fields, whilst initial notifications submit all required data fields. Furthermore, based on DH experience, it is assumed that annual activity involves tasks that are less time consuming than initial notification, such as responding to queries from industry.

In the absence of information, and for simplicity, it is assumed that the cost per modification and the cost of annual periodic activity per product line are equal to each other (across all product groups).

Therefore, **it is assumed that the cost per modification and the cost of annual periodic activity per product line are each 50% of the cost per initial notification** (within the product category). For cigarettes, roll your own and novel tobacco, this is represented as $0.5x$ for both modification and annual periodic.

It follows from these assumptions that the modification and annual costs associated with cigarettes, roll your own and novel tobacco are higher than for other tobacco products and herbal products. This seems reasonable given that there is a larger requirement for information for this product group, leading to larger costs of modifications and of annual activity (e.g. more data fields need to be updated, more queries need to be answered).

Table 7 – Relative cost assumptions per notification activity

Product group	Activity	Relative cost assumption	Paragraph Reference
Cigarettes, Roll Your Own, Novel Tobacco	Initial notification	x	(i)
	Modification	0.5x	(iv)
	Annual periodic	0.5x	(iv)
Other Tobacco Products	Initial notification	0.6x	(ii)
	Modification	0.3x	(iv)
	Annual periodic	0.3x	(iv)
Herbal Products	Initial notification	0.4x	(iii)
	Modification	0.2x	(iv)
	Annual periodic	0.2x	(iv)

Based on these assumptions of the relative cost of each activity, fees are set through an iterative process. As a starting point in this process, a fee corresponding to x (the cost per notification for cigarettes, roll your own and novel tobacco) is suggested, then all other fees are calculated using the relative cost assumptions in Table 7. It is tested whether this fee structure would bring in income that fully recovers costs. If not, then the starting point is revised upwards or downwards depending on whether it is a deficit or surplus, respectively. A surplus or deficit of less than 5% of total costs is considered as breakeven, to allow for a margin of error. Lastly, fees are rounded up slightly to the nearest £5.

The Department already receives annual data on tobacco products. Based on the experience of checking this data, and taking into account the enhanced reporting requirements of the Tobacco Products Directive, an assessment was made that a notification fee of around £250 per product would cover the costs associated with this service. Through the iterative process described above, this was revised downwards until the fee structure (as a whole) recovered total costs within the 5% margin (described in the previous paragraph).

Table 8 sets out the final iteration of this process, along with the information used in this process: estimated number of payments and relative cost assumptions (taken from Table 7). The estimated number of payments refers to the estimated number of product lines that will notify, for which modifications will be made to the database and for which annual periodic fee payments will be made annually from January 2017. These estimates are based on information on the current rate of initial and modification notifications received by DH, data from HMRC, industry and internet searches. This evidence suggested a range in the estimated number of annual periodic fee payments.. These sensitivities are reflected in the credible range for total estimated income from payments.

The central estimate of income from the resulting fee structure is **£134,000** (to three significant figures), from a credible range of £108,000 - £159,000.

Table 8 – Setting of fees in relation to relative cost assumptions and estimated income received by Government (with sensitivities provided in square brackets)

Product group	Activity	Estimated no. of payments	Relative cost assumption	Fee (rounded up to nearest £5)	Estimated Gov't income from fee
Cigarettes, Roll Your Own, Novel Tobacco	Initial notification	35	x	£220	£7,700
	Modification	35	0.5x	£110	£3,850
	Annual periodic	206 [194 – 218]	0.5x	£110	£22,600 [£21,240 – £23,980]
Other tobacco products	Initial notification	60	0.6x	£135	£8,100
	Modification	0	0.3x	£65	£0
	Annual periodic	1,379 [1,012 – 1,745]	0.3x	£65	£89,635 [65,780 – 113,425]
Herbal products	Initial notification	3	0.4x	£90	£270
	Modification	3	0.2x	£45	£135
	Annual periodic	30	0.2x	£45	£1,350
TOTAL ESTIMATED INCOME					£133,640 [£108,425 – £158,810]

Annex B – UK proportion of impact

Keeping in line with the methodology used by in the TPD Impact Assessment (IA)², a “GDP-based approach” is adopted to estimate the UK proportion of total costs to business. This approach assesses the impact of the fees on UK-based production, regardless of where the profits of this production may be repatriated to.

(1) Total direct cost of testing fees to UK-based businesses

The TPD2 IA estimated that for cigarette manufacturers, 8.1% of the costs will be UK based.³ That estimate takes into account the planned closure of the two remaining cigarette manufacturing plants in the UK in May 2016 and the second quarter of 2017. The combination of those two plants was estimated to represent approximately 85% of UK-based gross manufacturing value added consumed in the UK (44% from the one closing in May 2016, 41% from the other). It followed that this represented 4.1% of gross manufacturing value added in the UK over the 10-year review period of the IA. This figure was then adjusted upwards by 4 percentage points to 8.1% to reflect the possibility that in the counterfactual to TPD2 the factories may not have closed.

This analysis represents the UK proportion impact using the 8.1% for consistency with the TPD2 IA assumption. Based on this assumption, the total direct cost of testing fees to UK-based businesses is **£14,000** a year, out of a total **£174,000**. This figure is subject to the uncertainty of the estimated number of product lines submitted for testing.

(2) Total direct cost of notification fees to UK-based businesses

Table 9 sets out the calculation step-by-step (moving across columns from left to right). Total costs to business across each product group are calculated from estimated Government income in the final column of Table 8. UK-based proportions are calculated based on estimates used in TPD IA. However, estimates are only available for cigarettes, cigars, pipe tobacco and herbal products and as such are used as proxies for the whole product group to which they are assigned for this exercise.

The total direct cost of notification fees to UK-based businesses is estimated at **£11,000** out of a total **£134,000**.

² See paragraphs 221 – 233 in the Tobacco Products Directive Impact Assessment 18th April 2016 currently available at

http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwio7JbU2bPMAhXECMAKHARcAvAQFggcMAA&url=http%3A%2F%2Fwww.legislation.gov.uk%2Fukia%2F2016%2F109%2Fpdfs%2Fukia_20160109_en.pdf&usq=AFQjCNGP9EDWrlZhqYw1GQt0fE4j1MiK6g&bvm=bv.120853415,d.ZGg.

³ See paragraphs 222 – 225 in the TPD IA (see previous footnote for fuller reference).

Table 9 - Estimation of UK proportion of total costs to business

Product group	Total cost to business (to nearest thousand)	% UK-based	UK-based costs (to nearest thousand)	Source
Cigarettes, Roll Your Own Tobacco and Novel Tobacco	£34,000	8.1%	£3,000	Based on estimate of proportion of cigarette manufacturing that is based in the UK and impact of TPD on that proportion. (TPD IA para. 223-225)
Other Tobacco Products (OTP) ⁴	£98,000	5.8%	£6,000	Based on estimate of proportion of cigar and pipe tobacco manufacturing that is based in the UK and impact of TPD on that proportion (TPD IA para. 226-231).
Herbal products	£2,000	100%	£2,000	Based on estimate of proportion of herbal product manufacturing based in the UK.
Total	£134,000		£11,000	

⁴ OTP includes cigars, cigarillos, pipe tobacco, waterpipe, nasal snuff and chewing tobacco.

Annex C – Addressing evidence gaps through the consultation

We hope to address key evidence gaps through the consultation stage on the fees proposals in July 2016. The table below sets out key points of uncertainty in the analysis alongside the questions in the consultation document that could provoke the relevant responses from the public.

Uncertainty	Relevant consultation questions
Number of cigarette product lines submitted for testing in 2017/18 and subsequent years.	<ul style="list-style-type: none">• 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?
Number of notifications and modifications received in 2017/18 and subsequent years.	<ul style="list-style-type: none">• 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?• 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?
Relative workload assumptions across activities and product types	<ul style="list-style-type: none">• Do you agree or disagree with the levels of the proposed fees? If you disagree, please explain why.
UK impact of costs, particularly for the cigarette sector.	<ul style="list-style-type: none">• 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?