Service Specification

Testing for menthol characterising flavour in cigarettes notified for sale on the United Kingdom domestic market

**Purpose**

Public Health England (PHE) is seeking to commission one or more external partners to:

1. Conduct laboratory analysis of the yields of menthol emissions (or menthol analogue chemical alternatives) in specified combustible cigarette brands, in pursuance of Regulation 15 of the TRPR 2016 <http://www.legislation.gov.uk/uksi/2016/507/regulation/15/made> and in accordance with relevant ISO standards.
2. Subject to findings from the laboratory analysis, to convene a user group with a panel of smokers, to determine if identified tobacco products are compliant with TRPR Regulation 15 around the characterising flavour of those brands.

**Background**

Public Health England (PHE) is the expert national public health agency which fulfils the Secretary of State for Health’s statutory duty to protect health, address inequalities, and executes his power to promote the health and wellbeing of the nation.

PHE supports local authorities, and through them clinical commissioning groups, by providing evidence and knowledge on local health needs, alongside practical and professional advice on what to do to improve health, and by taking action nationally where it makes sense to do so.

The Tobacco Products Directive 2014/40/EU is a statutory obligation that placed tobacco product regulation obligations on Member States of the European Union (EU). This was transposed into UK law in 2016 by the Tobacco and Related Products Regulations (SI 507/2016 and SI 829/2015). The responsibility for overseeing compliance against these regulations has been conferred to PHE as the Competent Authority for tobacco and related products in the United Kingdom (UK).

New regulations came into force across EU member states in May 2020 which banned menthol as a characterising flavour in combustible tobacco cigarettes. PHE, as the Competent Authority, is responsible for ensuring that any tobacco-containing cigarettes that are notified by suppliers or manufacturers for sale across the UK are compliant with this regulation.

**Outline of Work**

The ban on menthol as a characterising flavour has generated the need for one-off testing to ascertain if identified cigarette brands are compliant with UK regulations. There are two distinct elements to this testing process, and the contract has been divided into three lots to provide flexibility to potentially award the distinct testing elements of the contract to different providers.

Potential providers may choose to bid on Lots one and two separately and to deliver both elements of the tender together in lot three, recognising that there may be a cost advantage in delivering both elements of the contract together.

**Any provider(s) must be able to demonstrate independence from the tobacco industry and have no commercial interest in the production of combustible tobacco filter devices.**

Outlines of the specific work for each lot are defined below.

**Lot 1 – Laboratory testing**

The provider must undertake laboratory testing of combustible cigarette products. PHE has identified 27 cigarette products of interest which will require laboratory testing for the presence of menthol and its analogues, with a smaller number of products (5) also being fully tested for control purposes. As well as the presence of menthol and its analogues within cigarette emissions, PHE require a summary of the individual levels of such chemicals identified. PHE is not specifying the method of analysis, but any process used would need to identify the presence (and level) of the specific ingredients below:

* Limonene
* Ethyl Salicylate
* Methyl Salicylate
* Menthol
* Eucalyptol
* Pulegone

The specific number and brands of cigarettes for testing will be identified by PHE and details supplied to the provider. The provider will be responsible for obtaining samples for testing. The cost of obtaining and transporting the samples will be borne by the appointed provider and should be included as part of the costs for contract delivery within their bid. The tobacco industry currently submits cigarette samples to an appointed contractor for tar, nicotine and carbon monoxide testing on a routine basis, so there may be opportunity to access products indirectly via this route.

A report on the outcome of the laboratory testing must be provided in electronic format. This report should highlight any brands that contain menthol (or menthol analogue), as well as the levels of such chemicals found within the emissions from each brand.

The successful applicant must have the capacity and skills required, including human resources, technical expertise, knowledge and experience of quality systems (e.g. ISO standards), smoking and analytical instruments, and electronic reporting systems. They should hold national and/or international accreditation in respect of the relevant smoke yield analysis as required in order to undertake and satisfy the outputs of the skill requirement. Finally, they should demonstrate practical experience of tobacco (combustible cigarette) technology and the principles of cigarette manufacturing.

**Lot 2 – User panel testing**

The provider must be able to establish (or have access to) a smoker user panel, and have experience of conducting blinded user tests, as well as producing analytical reports from such tests.

Based on results from the laboratory testing results in Lot 1, a panel of smokers must be convened by the successful provider to conduct user analysis of products. The specific number of cigarette brands put forward for user testing will be dependent on the results from the laboratory testing, therefore this phase must be conducted following the completion of Lot 1.

For bidding purposes, the provider should assume that up to a maximum of 32 cigarette brands will be taken forward to the user testing phase, including control samples to help establish a characterising flavour baseline. The user group will be required to blind sample all cigarette products and offer insight on any characterising flavour(s) that they experience from each product. Outcomes from this user testing should be collated, with both qualitative and quantitative results provided to PHE.

User testing may be conducted individually or in groups – to be agreed between PHE and the appointed provider. The number of participants within the user-testing is also to be agreed, but PHE would expect this to be a minimum of 50 people, all of whom are current smokers, and represent a diverse mix of genders, ages, and ethnicities.

The provider must produce a report from the user testing phase, identifying the number of participants who identified a characterising flavour within any of the products, as well as details of such flavours.

**Lot 3 – Laboratory Testing and User Panel testing combined**

Combination of Lots 1 and 2 as described above.

**Deliverables**

Lot 1: The provider will be required to deliver:

1. Independent laboratory analysis of the yields of menthol (or menthol analogue chemical alternatives) in emissions from specified cigarette brands, in pursuance of Regulation 15 of the TRPR 2016 <http://www.legislation.gov.uk/uksi/2016/507/regulation/15/made> in accordance with relevant ISO standards. Up to 32 cigarette brands will be specified for laboratory testing.
2. A written report following the laboratory testing, highlighting any brands that contain menthol (or menthol analogue), as well as the levels of such chemicals found within each product.
3. If the provider of Lot 1 (laboratory testing) does not also deliver Lot 2 (user panel testing), then they must agree to liaise with that provider to share cigarette samples, and agree costs for the transportation of those cigarette brands being taken forward for user panel testing.
4. Liaise with PHE throughout this process, and to host a virtual meeting to discuss findings.

Lot 2: The provider will be required to deliver:

1. User group testing with a panel of smokers, to gather insight on any characterising flavours derived by the smoker when using the brands provided. Up to 32 cigarette brands will be submitted for user-testing, dependent on the finding from the laboratory tests.
2. A written summary of the user-test findings, highlighting quantitative analysis of any characterising flavours identified, as well as any qualitative insights from the panel about specific products.
3. If the provider of Lot 2 has not also undertaken the laboratory testing, they must agree to work with the Lot 1 provider to agree transportation of the cigarette brands being taken forward for user testing.
4. Liaise with PHE throughout this process, and to host a virtual meeting to discuss findings.

**Lot 3: The provider will be required to deliver:**

Deliverables from Lots 1 and 2 above.

**Reporting arrangements**

The delivery partner(s) should work closely with PHE to plan, implement and report on the project.

The dissemination process for each lot should be inclusive of any local and national stakeholders identified by PHE.

**Data Handling and Provision**

All personal data (as defined within the General Data Protection Regulation - GDPR), collected, stored, analysed or shared must be carried out in compliance with the Data Protection Act 2018, GDPR and must conform with the policy statements specified in the PHE Information Governance Policy framework.

The successful provider(s) must adhere to the Freedom of Information Act (2000).

**Risk Management**

Applicants should submit, as part of their application, a summary explaining what they believe will be the key risks to delivering this project, and what contingencies they will put in place to deal with them.

A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a project objective, which includes any potential **conflicts of interest**. All risks should be identified. The summary should include an assessment of each risk, together with a rating of the risks likelihood and its impact on a project objective (using a high, medium or low classification for both). The risk assessment should also identify appropriate actions that would reduce or eliminate each risk, or its impact.

**Stakeholder and Public Involvement**

The provider will be undertaking direct engagement with members of the public as part of the smoker user panel. The provider will be expected to submit as part of their application their mechanism for engaging with such a panel.

**Accessibility**

<https://www.gov.uk/guidance/accessibility-requirements-for-public-sector-websites-and-apps>

<https://gds.blog.gov.uk/2018/06/20/creating-the-uk-governments-accessibility-empathy-lab/>

<https://www.gov.uk/service-manual/helping-people-to-use-your-service/getting-an-accessibility-audit>

**Delivery Timescale**

Lot 1: The provider of will be expected to complete all laboratory testing, provide a written report and host a virtual sign-off meeting with PHE by 24th September 2021.

Lot 2: The provider will be expected to complete the user panel testing, provide a written report and host a virtual sign-off meeting with PHE by 5th November 2021.

Lot 3: Deadlines as for Lots 1 and 2 above:

Laboratory testing element by 24th September 2021.

User Panel testing element by 5th November 2021.

**Contract Period**

The contract will begin on 9th August 2021 and will conclude on 5th November 2021 as per the commissioning timetable below.

**Contact Point(s)**

It is expected that the supplier(s) will appoint a named Lead Manager who will be the main point of contact with Public Health England.

The key contact points at PHE will be Samantha Gordon, Martyn Willmore, and Martin Dockrell within the tobacco control team. All members of staff will be available for telephone or face to face advice throughout the project lifetime. PHE can facilitate discussions with other topics experts from within PHE and other key partners.

**Costs**

The provider will need to give a detailed breakdown of their costs. Please note that applicants will need to demonstrate value for money.

The overall contract value for completion of both lots will be for a maximum of £50,000 (excluding VAT). It is expected that each lot will have a value of around £25,000 (excluding VAT).

**Application Process**

Applications should be submitted electronically, clearly setting out if the bidder wished to apply for Lots 1 or 2 (or Lot 3, both). Applicants should include the following documentation:

* Supporting statement setting out and establishing suitability to undertake the project, including evidence of carrying out work of a similar nature
* Project outline including, where appropriate, details of evaluation plan, communications plan & methodology, evaluation logic model, timescales and stakeholder engagement plan.
* Budget (including detailed breakdown of spend)
* Risk mapping and associated risk register, including any potential conflicts of interest
* Evaluation and project team CVs

Word count (excluding Project Team CVs) is a max of 2,000 words per document.

Applications will be reviewed by an internal PHE panel and applicants will be informed electronically of the result.

If two applications are scored identically then both applicants will be invited to a verbal presentation to decide the outcome.

**Selection Criteria**

Criteria used by members of the PHE panel to assess applications for funding from the project include:

1. **RELEVANCE** of the proposed project plan and evaluation methodology to the aims and objectives of the project
2. **QUALITY** of the work plan and proposed management arrangements
3. **STRENGTH** of the project team
4. **IMPACT** of the proposed work
5. **VALUE** for money (justification of the proposed costs)
6. **INVOLVEMENT** of key partners and the public

**Commissioning Timetable**

It is anticipated that commissioning of this project will occur to the following approximate timetable:

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| --- | --- |
| **Date** | **Action** |
| **09.07.2021** | Issue of invitation to tender via Atamis |
| **30.07.2021** | Deadline for receipt of applications |
| **04.08.2021** | Dates for potential clarification meetings |
| **06.08.2021** | Notification of outcome of applications review |
| **09.08.2021** | Award of contract |
| **05.11.2021** | Project completion |