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# TPD

THE TOBACCO PRODUCTS DIRECTIVE

## COMPLIANCE GUIDE





# EL-Science

## Who We Are

Dedicated solely to eliquid analysis and manufacture, EL-Science is one of the most experienced e-cigarette testing laboratories in Europe. Our leading team of scientists are comprised of analytical, production, flavour and organic chemists, who work closely with our consultant toxicologists.

**W**e understand that ensuring your eliquid products and devices are compliant with the Tobacco Products Directive (TPD) is paramount to maintaining and growing your successful business. As such, we have put together a service offering that we feel encompasses all aspects of TPD compliance.

We will work with you every step of the way, helping you reformulate your flavours based on analytical results and toxicological assessments. Our goal is to not only provide the analytical data you require for your TPD submission, but to also help you maintain your eliquid's flavour profile, whilst reducing any individual components of toxicological concern.

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# WHAT IS THE TPD?

The Tobacco Products Directive (TPD) is an EU directive which details tobacco control in all European Union member states. The latest TPD includes the governing of electronic cigarette regulation.

## Article 20 of the TPD states:

Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market... The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:


- 1 the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;
- 2 a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- 3 toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;
- 4 information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
- 5 a description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;
- 6 a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;
- 7 a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

The TPD comes into effect on:

**20th May  
2016**







There are also a number of restrictions that apply, as follows:

- 1 Refill containers are not to exceed 10 mL.
- 2 Cartridges and tanks are not to exceed 2 mL.
- 3 Nicotine concentration is not to exceed 20 mg/mL.
- 4 Eliquids are not to contain additives, including vitamins, energy stimulants, and colourants, amongst others.
- 5 Except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form may be used.
- 6 Electronic cigarettes must deliver nicotine doses at consistent levels under normal conditions of use.
- 7 Electronic cigarettes and refill containers must be child- and tamper-proof, protected against breakage and leakage and must have a mechanism that ensures refilling without leakage.



Strict requirements with regard to labelling must also be followed. Unit packets of electronic cigarettes and refill containers must include:

- 1 A leaflet detailing the following information:
  - a. instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers.
  - b. contra-indications.
  - c. warnings for specific risk groups.
  - d. possible adverse effects.
  - e. addictiveness and toxicity.
  - f. contact details of the manufacturer or importer and a legal or natural contact person within the Union.

Ingredients  
& General  
Warnings

Barcode

Contact Information

Warning  
Symbols



Strength & Batch Number

Volume

- 2 Outside packaging/labelling detailing the following information:

- a. A list of all ingredients contained in the product in descending order of the weight.
- b. An indication of the nicotine content of the product and the delivery per dose.
- c. The batch number.
- d. A recommendation to keep the product out of reach of children.
- e. The following health warning: 'This product contains nicotine which is a highly addictive substance.'
- f. Health warnings.

The notification procedure in the UK is being managed by the MHRA (Medicines and Healthcare Products Regulatory Authority).





# HOW CAN EL-SCIENCE HELP?

**E**L-Science is here to help you with all aspects of TPD compliance, from ensuring your products are labelled correctly and the appropriate information is included on the accompanying leaflet, to compositional analysis of your eliquid and emissions testing.

The following summarises the different areas of TPD compliance that we can provide a solution for:





## Hardware

All hardware products that contain or could contain nicotine in the form of eliquid require a TPD submission.

Hardware importers or manufacturers must submit technical dossiers to the MHRA which detail:

- 1 Leachability testing.
- 2 Leak free filling mechanism testing.
- 3 Emissions testing. This includes determining whether a particular piece of hardware is liable to thermally degrade eliquid components into compounds that are of toxicological concern, measuring any metals that may be transferred from the hardware to the eliquid aerosol, as well as measuring nicotine dose.

EL-Science will be conducting the above testing in-house for a large array of popular hardware options. Customers can buy the data directly from us for an upfront fee, or can purchase the hardware through us at a price that covers inclusion of the TPD submission. The former would be recommended for customers who sell high volumes of the hardware unit in question, whereas the latter would be better suited to those who deal in lower volume sales.



## Eliquid

**W**e offer compositional analysis of your eliquid and emissions via GC-MS, which can be used to back up a full chemical breakdown supplied by a concentrate manufacturer or to provide the qualitative and quantitative information on your eliquid in the first instance.

**W**e have identified a list of common flavour compounds that we consider to be of primary interest. This includes compounds that we have seen over and over again during eliquid analysis and those that have been highlighted as being of significance by our toxicological company, our internal and external flavourists, including our 2 PhD organic chemists, and the concentrate manufacturers who are working closely with us. We are funding, along with a number of other large eliquid manufacturers, the toxicological profiling of these compounds. This information, which will be made available to our customers for the purposes of submitting their technical dossiers to the MHRA, will allow us to identify any eliquid/flavour components of particular concern to inhalation health, will justify the use or inclusion of any others, and will provide thresholds below which these compounds are considered to not be of toxicological concern to the end product user.

Any compounds that are identified analytically that are not on the list, will be investigated to determine whether they are there as a result of the thermal degradation of a known and expected eliquid component or if they are present as the result of contamination during concentrate or eliquid manufacture.





## Reformulation

**W**here an eLiquid requires modification, we will work with you to modify and reformulate your recipes as required in order to be compliant.

We have no doubt that the majority of eLiquid flavours will change over time as a result of TPD compliance, however, we aim to help you maintain the flavour profile of your eLiquid as much as possible to ensure that your eLiquids keep their originality. Our dedicated Flavour Chemists can offer synthetic alternatives to problematic concentrates or individual components, and will work with you to ensure the integrity of your product's sensory profile whilst reducing or entirely eliminating the compounds of toxicological concern.



## TPD Compliant eliquid concentrates

**O**ur range of specifically designed eliquid flavour concentrates are fully TPD compliant. Our flavour concentrates have been stringently assessed to toxicological thresholds, and customers can use our unique modelling software, which allows you to see the toxicological implications of mixing multiple concentrates together whilst developing your eliquid product, giving you full control. The benefit of using our TPD compliant concentrates is that we hold the full compositional and toxicological information relating to each raw chemical ingredient, which may then be used within TPD submissions and gives you confidence that your resultant flavour is TPD compliant.

## TPD Compliant Augmented eliquid concentrates

**W**e are also able to augment or modify our base TPD compliant concentrates with specific flavour chemicals in order to create customer-bespoke concentrates that are unique to your business. This innovative new approach allows you to create your very own flavour concentrates, which no one else will have access to, and to distinguish your company from the hundreds of others out there, all of which are using the same flavour concentrates from the same flavour houses.





## Other Services

We are also launching a number of other services that tie into the above:

### 1 **Product Liability Insurance**

We are developing a bespoke insurance product that will have favourable and industry specific exclusions terms and will include up to 40% public liability insurance discount.

### 2 **EL-Science Membership**

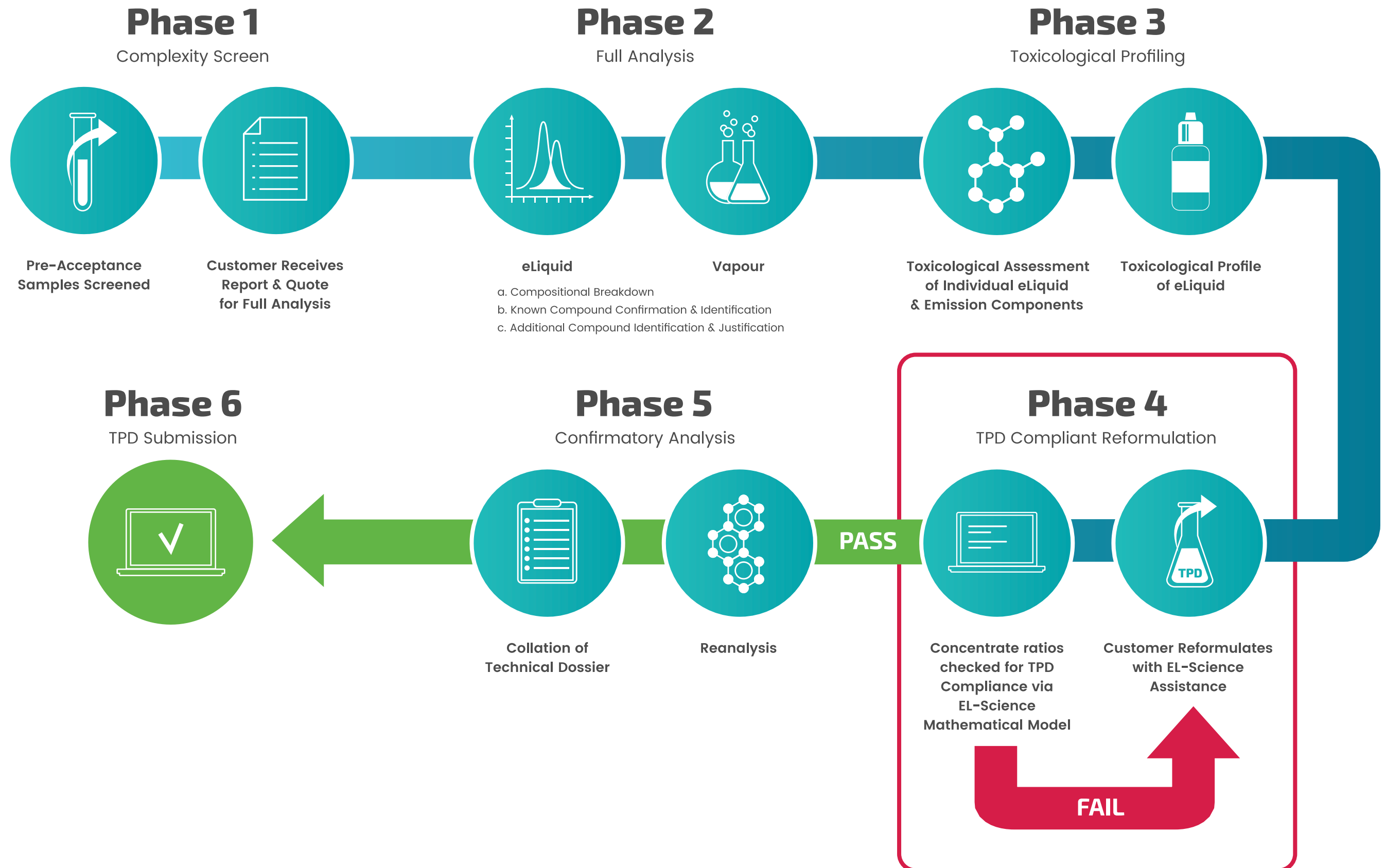
Membership includes discounted batch testing, discounted TPD and post-TPD flavour development fees, use of the Flavour Development Lab and its resources (including being able to pick our chemists' brains), as well as access to our Compliance Team.

### 3 **TPD Compliant Flavour Development**

Our dedicated Flavour Lab holds stock of one of the largest flavour concentrate libraries in Europe. We also have access to the individual raw material chemical components that, when mixed, result in any smell, taste and flavour profile that you would like to create. As such, we are able to assist you with developing eliquid flavours that meet TPD requirements. Adding known and controlled concentrations of these flavour chemicals to develop new eliquids greatly reduces the overall cost related to compositional and supporting data for future TPD submissions.



# STEPS TO TPD SUBMISSION







# PRICING

## 1 **Pre-Acceptance Samples: £200 +VAT per sample**

Pre-Acceptance Samples will undergo a Complexity Screen to allow EL-Science to get an understanding of the complexity of the flavour profile. This allows us to customise your quote as much as possible, based on the level of work required to reach TPD compliancy. The fee of £200 +VAT per sample will be deducted from the total cost of the full TPD analysis of that sample.

## 2 **Full TPD Analysis: POA**

Full TPD Analysis includes compositional analysis of both the eliquid and its emissions, toxicological profiling of individual ingredient components, as well as the overall eliquid itself, and preparation of TPD notifications for submission.

Discounts may be possible for Full Analysis based on the volume of samples submitted, and payment can be spread over the period of analysis.

## 3 **TPD Compliant Reformulation:** This will be quoted for based on your specific requirements, but for low complexity samples may be included in the cost of Full Analysis.

MHRA fees are separate to those quoted by EL-Science, and will need to be paid additionally. Please see overleaf for MHRA pricing.



# MHRA Pricing

Currently, the MHRA are detailing pricing as follows:

- 1 Notification Fee for New Product: **£220**
- 2 Ongoing Annual Periodic Fee: **£60 per year**
- 3 Notification of a Modification to an Existing Product: **£110**

## Let's Work Together

We believe that working together as an industry will help set the standard with regard to TPD compliance, and will set our partners and customers aside as being responsible and ethical eliquid manufacturers.

For more information please call **+44 (0) 1733 352 553**,

email **[contact@elscience.co.uk](mailto:contact@elscience.co.uk)**

or visit our website **[www.elscience.co.uk](http://www.elscience.co.uk)**.