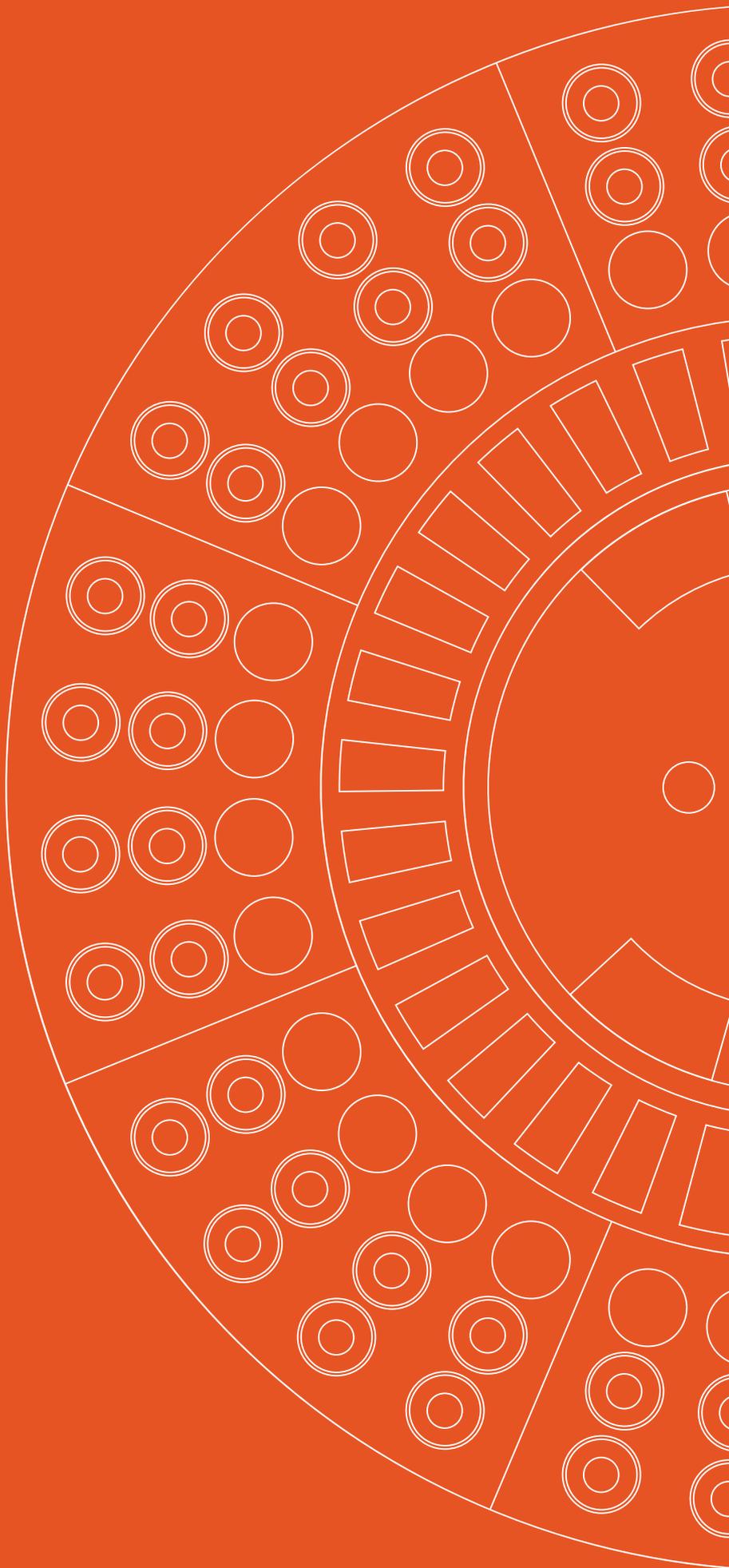


Regulatory  
Compliance

xyfil

> E-liquid Solutions <

[www.xyfil.com](http://www.xyfil.com)





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# REGULATORY COMPLIANCE

E-liquid Safety and Regulatory Compliance is a prerequisite for any successful e-liquid brand or business. Consumers expect safety assurance as standard. Currently, compliance has been introduced and enforced in the EU market, and soon it will be a requirement within many of the larger markets worldwide.

Analysis of e-liquid is an essential activity for the industry and the consequences of getting due diligence obligations wrong can be severe, leading to loss of business, reputation, public injury, fines or even imprisonment. Choosing the right provider is critical to ensure all concerns are adequately addressed.

At Xyfil, we work closely with the Medicines and Healthcare products Regulatory Agency (MHRA), and have invested in the expertise and capability to take your business through the required regulatory framework. Our in house team of experts are able to perform the necessary toxicological evaluations on the compounds detected during the analysis of your e-liquid and its emissions. More critically, we also know how to gather this data into the format required by all European member states and complete the required submission for your business. We also know what won't be compliant, thereby saving you time and money in undertaking an application that could be rejected six months later.

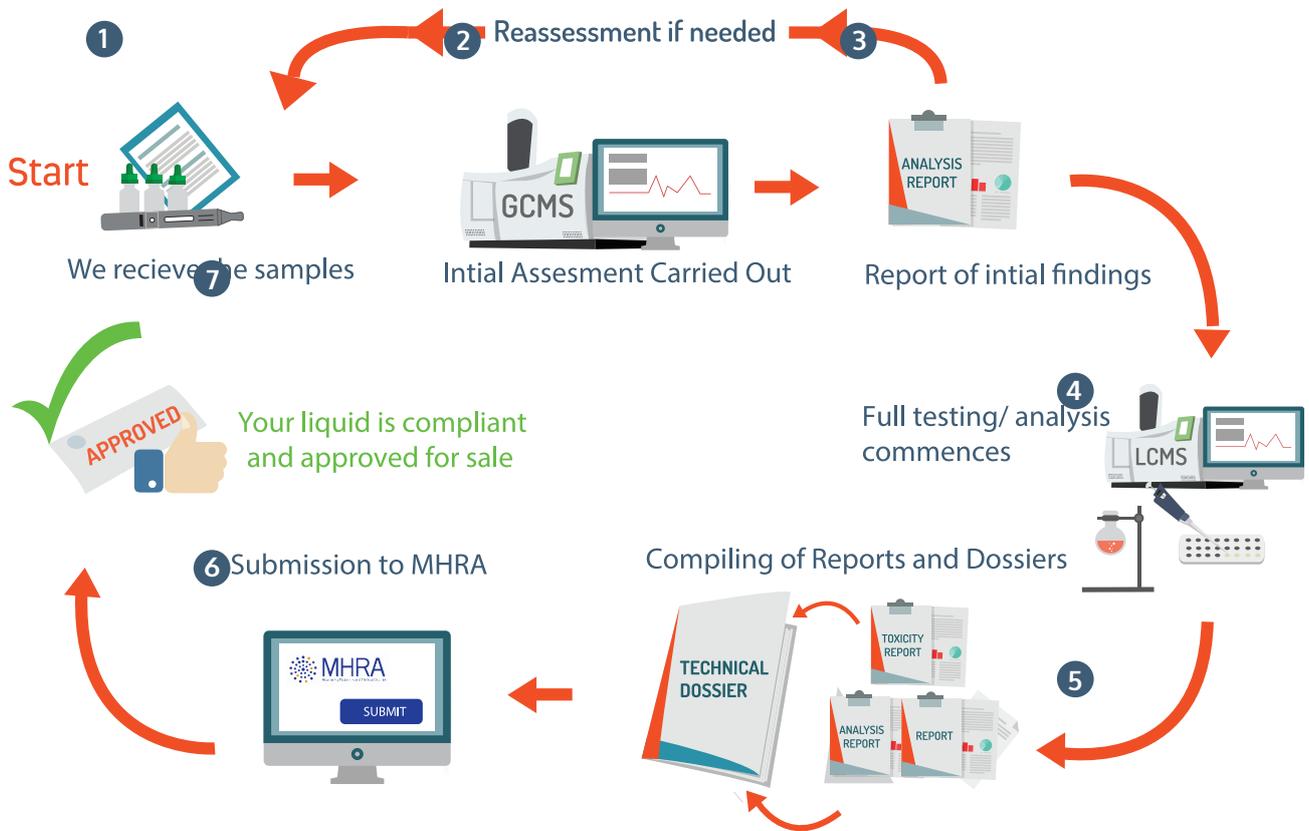
In terms of the analysis itself, our methods have been developed and validated in partnership with Agenda 1, the analytical arm of Concept Life Sciences Group. Accredited by the MHRA and conforming to ISO 9001 standards, Agenda 1 delivers analytical expertise across all scientific commercial market sectors. Their experts and analytical suite, when coupled with our in-house expertise in toxicology and the compliance process, means we are truly leading the way in the industry.

This winning combination means you can have confidence in both the validity of the results we generate and the notifications we submit. When we tell you your liquid is compliant, you can be assured that no independent analysis will throw up any unexpected surprises which could disrupt your business, or damage your reputation.

At Xyfil, we have experimented extensively using GCMS and CMS/QTOF equipment and have concluded that it is impossible to perform a full analysis using simply one technique (GC/MS). This is why; we employ a full raft of analytical methods; to ensure we deliver complete and trustworthy compliance in the most cost effective way. Our support services include:

- ✓ Full Composition Analysis;
- ✓ Comprehensive Emissions Testing;
- ✓ Toxicological & Safety Assessments;
- ✓ Metals Testing;
- ✓ Leakage testing;
- ✓ CLP Classification of the SKU
- ✓ Testing Refill Mechanisms;
- ✓ User/Product leaflet design
- ✓ Nicotine Dosage & Uptake;
- ✓ Regulatory Notification;
- ✓ Full TPD Notification Submissions;
- ✓ Packaging Compliance
- ✓ Vigilance & Annual Reporting

# THE PROCESS



## TESTING & ANALYSIS

Full compositional analysis of all e-liquids and emissions involves using various techniques and methods which include:

- ✓ Nicotine content of E-cigarette liquids or condensates by GC-FID.
- ✓ Nicotine content of E-cigarette liquids emissions by GC-FID.
- ✓ Emissions Assay of E-cigarette liquid or condensates by DAD-HPLC (Formaldehyde, Acetaldehyde, Acrolein, Diacetyl & Pentane 2,3 dione).
- ✓ Emissions Assay of E-cigarette liquid emissions by DAD-HPLC (Formaldehyde, Acetaldehyde, Acrolein, Diacetyl & Pentane 2,3 dione).
- ✓ Glycols and Glycerine content of E-cigarette liquid or condensate by GC-FID.
- ✓ Glycols and Glycerine content of E-cigarette liquid emissions by GC-FID.
- ✓ Determination of metals in E-cigarettes liquid condensates by Atomic Absorption.
- ✓ Determination of water content by Karl Fischer.

## **TROUBLESHOOTING SERVICE**

If we analyse your e-liquid and find it will not pass for any reason, all is not lost. We offer a troubleshooting service to help determine which flavour concentrate is providing the toxic or addictive compounds. You can then look at finding a safe alternative for that flavour concentrate.

## **TOXICOLOGICAL EVALUATION**

Toxicological evaluations are performed based on the compounds detected and dosage calculations from earlier findings and results. If we can demonstrate no known risk based on the levels of any given compound in your product, even if that compound is toxic at higher dosage levels, there will still be no problem notifying your product. After all, the difference between a drug and a poison is the dose.

## **PRODUCT SAFETY & PACKAGING**

Guidance is provided for product safety and information leaflets.

## **COMPILING DOSSIERS & SUBMISSION**

Once all the analysis and testing has concluded, a complete technical dossier is compiled and generated for submission.

If you would like to know more about timelines or any of the listed services speak to our compliance team for more details on 01772 888 778 or reach us at [compliance@xyfil.com](mailto:compliance@xyfil.com).

# COMPLIANCE PRICING

We appreciate that solutions must be commercially viable and can help achieve that crucial balance between compliance, quality and profit. Our clients range from start-up businesses through to established retail brands.

We pride ourselves on providing a wide range of professional and practical support to enable businesses to meet their due diligence requirements. Core support services are listed for costing purposes.

We are able to offer a complete and cost effective package for full TPD compliance to our clients.

	PRICE/UNIT	DESCRIPTION
<b>COMPLIANCE FOR LIQUIDS</b>		
Full Compliance for liquid	£600	
Subsequent variants	£200	This applies to variants such as nicotine strength, diluent ratio's (not variations of flavour)
<b>COMPLIANCE FOR DEVICES</b>		
Disposable device, refillable tanks or cartridges	£950	Comprehensive submission
Annual Compliance	£100	Per SKU. Covers the legal responsibility for annual reporting requirements to the MHRA
<b>MHRA SUBMISSION FEES</b>		
New notification fee	£150	
Substantial modification fee	£80	These fees are payable directly to
Annual fee	£60	the MHRA upon submission of notifications

Note: Toxicology only needs to be performed on the highest nicotine strength.

\*All pricing information stated is correct at time of printing and subject to change without notice. Please check with us to confirm current pricing.

## GOVERNMENT FEES

Value	Name	Government Fees (Fresh)	Government Fees (Modification)	Government Fees (Annual)	How to pay?
AT	Austria	Awaiting Response	Awaiting Response	Awaiting Response	
BE	Belgium	€165,00	No Fees	No Fees	
BG	Bulgaria	No Fees	No Fees	No Fees	
CY	Cyprus	Unknown	Unknown	Unknown	
CZ	Czech Republic	No Fees	No Fees	Awaiting Response	
DK	Denmark	~€4,946 (DKK 36,900)	Unknown	~€2,159,00 (DKK 14,700)	
DE	Germany	No Fees	No Fees	Awaiting Response	
EE	Estonia	No Fees	No Fees	No Fees	
GR	Greece	€56,00	Unknown	Awaiting Response	
ES	Spain	Law is not transposed yet	Law is not transposed yet	Law is not transposed yet	
FI	Finland	€150,00	Unknown	Unknown	The authority is not able to give any estimation on when the invoices will be sent.
FR	France	€295,00	No Fees	120 (to be paid before 31 march of each year)	
HR	Croatia	Awaiting Response	Awaiting Response	Awaiting Response	
HU	Hungary	~€1,543 (HUF 475,000)	~€995 (HUF 306,000) including changes to Brand Name & Nic Strength	Awaiting Response	Fees must be paid to the National Institute of Pharmacy and Health Food (OGYE), account number: 10032000-00290050
IE	Ireland	No Fees	No Fees	Awaiting Response	
IT	Italy	Not yet decided by the authority	Not yet decided by the authority	Not yet decided by the authority	
LT	Lithuania	No Fees	No Fees	No Fees	
LU	Luxembourg	€5,000,00	Unknown	No Fees	
LV	Latvia	€121,96	Unknown	€75,69	EUR 59 98 for Assessment of the presence of prohibited or restricted additives in tobacco products and the characteristic aroma of cigarettes or spaghetti?
MT	Malta	No Fees	No Fees	No Fees	
NL	Netherlands	€44,85	€44,85	Unknown	
PL	Poland	Medium-sized enterprises: ~€490,00 (PLN 2137,85) Small and micro- enterprises: ~€295,00 (PLN 1282,71) other enterprises: ~€980,00 (PLN 4275,69)	Unknown	Unknown	The manufacturer or importer shall pay the fee into the bank account indicated by the Inspector, within 14 days of receiving the instruction to pay, for receiving, storing, handling, analyzing and publishing information on tobacco products submitted.
PT	Portugal	No Fees (annual fees only)	Unknown	€1,000,00	
RO	Romania	Awaiting Response	Awaiting Response	Awaiting Response	
SI	Slovenia	Law is not transposed yet	Law is not transposed yet	Law is not transposed yet	
SK	Slovakia	No Fees	No Fees	No Fees	
SE	Sweden	Awaiting Response	Awaiting Response	Awaiting Response	
GB	United Kingdom	€150,00	€80,00	€60,00	Annual Fees to be paid by 1st April of each year.

# INDIVIDUAL COMPONENTS

If you only require particular parts of the service, such as toxicology but not analysis we are able to offer individual components, such as R&D when full compliance is not required; we have broken down segments into single individual tests and assessments priced accordingly in this table.

COMPONENTS	PRICE/UNIT	DESCRIPTION
Comprehensive Liquid & Emissions testing	£400	Per sample
Toxicology and Safety Assessments	£150	Per Assessment
Metals Testing - For Devices	£750	Per Sample
TPD Notification preparation and Submissions	£200	Per SKU
Subsequent Variants (Nicotine & Ratio's)	£200	Per SKU

Safety Data Sheet- £150- Per Assessment

Note: Toxicology only needs to be performed on the highest nicotine strength and the report will be provided under NDA-not for resale or distribution.

## COMPREHENSIVE EMISSIONS TESTING

- Nicotine dosage and uptake;
- Nicotine related impurities;
- VOCs (with targeted analysis of Formaldehyde, Acetaldehyde, Acrolein, Diacetyl, Acetylpropionyl, Diethylene Glycol, and Ethylene Glycol);
- Propylene glycol & glycerol content;

All analysis is undertaken using multiple methods using: HPLC, GC/MS, a number of different kinds of LC/MS/MS & also Karl Fisher tests.

## METALS TESTING

- Involves analysing for specific metal ions using Atomic Absorption
- Only a requirement for hardware;

## TOXICOLOGY AND SAFETY ASSESSMENTS

- Searching scientific databases for relevant studies;
- Analysing toxicity by inhalation in those studies;
- Performing dosage calculations based on levels detected in your product;
- Determining safety based on toxicology & dosage calculations;

## TPD NOTIFICATION PREPARATION AND SUBMISSIONS

- Collating the technical notification dossier;
- Submitting the prepared dossier using EU-CEG portal;
- Preparation of safety data sheets

## **YOUR PARTNER**

Xyfil is an end to end e-liquid solutions provider that can take our clients from concept to manufacturing to compliance. Our group structure includes a manufacturing, branding, flavour development and retail arm. This places us in a unique and winning position to appreciate our clients concerns and worries when it comes to compliance. Chances are that we have experienced the same challenges ourselves. Whether it is concerns about the impact of compliance on your unique flavour compositions, recipe confidentiality or incomplete information from your flavour houses - Xyfil is uniquely placed and experienced to handle your compliance challenges in a professional and competent manner.

## **YOUR INTELLECTUAL PROPERTY**

At Xyfil, we value that your recipes are your asset and therefore we treat them with the strictest confidentiality - we don't even ask you for them. We do not require you to tell us what flavourings you are using, in what quantity, from which supplier, in order for us to analyse your liquid and complete your notification. Your formulation is entirely your property and does not need to be disclosed. In the instance we may need your flavours as part of our troubleshooting service; we would again protect this information by asking that you anonymise your flavours.

## **PROVISION OF CAS NUMBERS**

Some concentrate providers are good enough to provide you with the CAS numbers for all ingredients which go into their flavour concentrate; others do not. If you are able to give us any associated CAS data it will help us, but please be assured we can still perform the work even without them.

## **ENTRY TO NEW MARKETS**

Beyond the EU's Tobacco Products Directive, as other markets announce forthcoming regulations within the industry; Xyfil's commitment to investing in high calibre research scientists and relevant analytical equipment ensures that we remain at the forefront of learning and are equipped to help your brand expand into new markets.



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#### GET IN TOUCH

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