PAS 54115:2015

Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products – Manufacture, importation, testing and labelling – Guide

ECITA
Electronic Cigarette Industry Trade Association

bsi.

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Foreword

This PAS was sponsored by the Electronic Cigarette Industry Trade Association, ECITA (EU) Ltd. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 July 2015.

Acknowledgement is given to the following organizations that were involved in the development of this PAS as members of the steering group:

- Electronic Cigarette Consumer Association of the United Kingdom (ECCA UK)
- Knowledge Action Change (KAChange)
- New Nicotine Alliance
- Nicoventures
- Totally Wicked Ltd
- Trading Standards Institute

Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a guide to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

As a guide, this PAS takes the form of guidance and recommendations. It should not be quoted as if it were a specification or a code of practice and claims of compliance cannot be made to it.

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The guidance in this standard is presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this PAS cannot confer immunity from legal obligations.

Particular attention is drawn to the following specific regulations:

- General Product Safety Directive 2001/83/EC (as amended in 2004) [1]
- Low Voltage Directive 2006/95/EC [2]
- Electromagnetic Compatibility Directive 2004/108/EC [3]
- Restriction of Hazardous Substances Directive 2011/65/EU [4]
- Classification Labelling and Packaging Regulation (EC) No. 1272/2008 [5]
- Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No. 1907/2006 [6]
- Waste Electrical and Electronic Equipment Directive 2012/19/EU [7]
- Batteries and Accumulators and Waste Batteries and Accumulators (Battery) Directive 2006/66/EC [8]
- Radio Equipment and Telecommunications Terminal Equipment Directive 1999/5/EC [9]
- Medicinal Products Directive 2001/83/EC [10]
- Tobacco Products Directive 2014/40/EU [11]
- Control of Poisons and Explosives Precursors Regulations 2015 [12]
- Poisons Act 1972 [13]
- Control of Substances Hazardous to Health Regulations 2002 [14]
- Personal Protective Equipment (PPE) At Work Regulations 2002 [15]
- Health and Safety (First-Aid) Regulations 1981 [16]
- Health and Safety At Work etc. Act 1974 [17]

Attention is also drawn to the Committee of Advertising Practice and Committee of Broadcasting Practice's *New rules for the marketing of e-cigarettes* (Oct 2014) [18] and the ECITA Industry Standard of Excellence (ISE), Public Edition [19], available from www.ecita.org.uk.

Introduction

Background

Electronic cigarettes (e-cigs) and other vaping products (VP) are a rapidly growing market sector. It is prudent, therefore, to provide guidance on manufacturing, importing, labelling and marketing practices, to highlight the importance of safety and quality for consumers who wish to have access to VP.

The approach taken for this guidance

This guidance offers good practice solutions which are achievable and enforceable, with the minimum burden placed both on businesses operating in the sector, and on government enforcement agencies.

The guidance outlined in this PAS is designed to help provide information and recommendations on product safety and quality to meet consumer needs, minimize negative impacts on the environment, enable swift product innovation, and maintain technological neutrality.

This PAS covers:

a) purity of e-liquid ingredients in manufacture;
b) contaminants arising from device materials and potential emissions from device operation;
c) electrical safety;
d) metals and carbonyls in emissions.

NOTE 1 *This PAS maintains technological neutrality through its recommendations for producers. This means that safety and quality guidance is not technology-specific, but focussed on the outcome of the test/assessment. This is important so as not to disadvantage products with particular technologies compared to other products, as well as to future-proof the PAS, insofar as this is possible for emerging technologies.*

Recent regulatory assessment of toxicological data on nicotine [20] has determined that e-liquids containing up to 2.5% w/w nicotine concentration do not require a hazard classification for acute oral and/or dermal toxicity in accordance with the Classification Labelling and Packaging Regulation (EC) No. 172/2008 (CLP) [5].

NOTE 2 *The harmonized classification of nicotine under CLP is currently under review at the European level, so this might change after publication of this PAS.*

Why is guidance on safety and quality necessary?

Safety and quality guidance is necessary to provide minimum expectations to producers and reassurance both to regulators and the public that product safety and quality is maintained across batches and can be reliably demonstrated with documentary evidence.

How can guidance be created for products with such diversity?

Guidance needs to be relevant to all the various product types currently available, as well as to those that will be developed. Not all elements of this guide will apply to every product, but the definitions can be used to identify guidance relevant to specific products, or parts of products, within this diverse sector.

It is very important that guidance covers vaping products without nicotine (VPWNs), as well as VPs containing nicotine, because safety and quality concerns are equally relevant to VPs which do not contain nicotine, since all such products are designed for inhalation.

What about consumers mixing e-liquid for themselves?

E-liquid is sold in different forms for different sectors of the market. For the DIY market, base liquids (with and/or without nicotine) are provided, usually together with flavour concentrates for the consumer to blend for themselves. The toxicity of the nicotine-containing base liquid can be mitigated by providing detailed instructions for handling and dilution.

NOTE 3 *Attention is drawn to CLP [5].*

How does this guide help?

In order for producers and distributors of VP to be able to provide reassurance to the public, they need to know how their products are made, what goes into them, and what emissions are produced during their use. The guidance in this PAS is provided to assist producers and distributors in assessing their products for these factors, so that their documentary evidence will be robust.

1 Scope

This PAS gives guidance for the manufacture, importation, labelling, marketing and sale of vaping products (VP) including electronic cigarettes, e-shisha, DIY e-liquid mixing kits, and directly related products.

The PAS also gives guidance focussing on the purity of e-liquid ingredients in manufacture, contaminants arising from device materials and potential emissions from device operation, electrical safety, and metals and carbonyls in emissions. The PAS describes a test solution-liquid, and an outline for the toxicological and chemical analysis of emissions.

The PAS also gives guidance for the safety of batteries and chargers.

The PAS refers to existing safety guidance already in place which are relevant to this sector.

The PAS is applicable to producers and distributors of VP in the UK, and forms a guide for commercial operations in this sector.

The PAS is also applicable to laboratories and testing houses engaged in, or planning to be engaged in, the testing of VP.

This PAS is not intended to cover those VP which are licensed as medicinal products or medical devices. It is not intended to cover "heat not burn" or other tobacco products. It does not cover wireless communication features which may be built in to vaping devices, but does cover the vaping products themselves. It also does not cover products which can be used in or as VP, but which are sold for other purposes, e.g. food flavourings sold in supermarkets.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 862, *Packaging – Child-resistant packaging – Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*

BS EN 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

BS EN ISO 8317, *Child-resistant packaging – Requirements and testing procedures for reclosable packages*

European Pharmacopoeia, *Purified water* Monograph 0008

European Pharmacopoeia, *Nicotine* Monograph 1452

European Pharmacopoeia, *Glycerol* Monograph 0496

European Pharmacopoeia, *Propylene glycol* Monograph 0430

United States Pharmacopeia, *Propylene Glycol* Monograph

United States Pharmacopeia, *Purified water* Monograph

United States Pharmacopeia, *Nicotine* Monograph

United States Pharmacopeia, *Glycerin* Monograph

3 Terms, definitions and abbreviations

For the purposes of this PAS, the following terms and definitions apply.

3.1 Terms and definitions

3.1.1 accessory

product for use with vaping products (**3.1.41**) which does not inherently contain e-liquid (**3.1.15**), and is not itself, nor is it a component of, an electrical or electronic functional component

NOTE For example, drip tip, case, etc.

3.1.2 atomizer

coil and **wick** (**3.1.44**) assembly to which power is supplied to heat **e-liquid** (**3.1.15**) to help form **vapour** (**3.1.43**) for inhalation

NOTE An atomizer can be capable of having its heating coil constructed by end users. These are referred to as "rebuildable atomizers".

3.1.3 base liquid

mixture of glycerol, propylene glycol and/or other diluents to which nicotine can be added to create an input for **e-liquid** (**3.1.15**) manufacturing, and to which **flavourings** (**3.1.19**) can be added

3.1.4 batch specification

document itemizing the inputs and processes for manufacturing a product batch

3.1.5 cartomizer

disposable **cartridge** (**3.1.6**) with in-built **atomizer** (**3.1.4**)

*NOTE These can either use a filler material to hold liquid, or hold liquid in a **tank** (3.1.38) system.*

3.1.6 cartridge

part of a multi-piece **electronic cigarette** (**3.1.14**) that contains liquid but not an **atomizer** (**3.1.4**)

3.1.7 compound

individual chemical species used in combination with other chemicals to produce **ingredients** (**3.1.23**) for **e-liquid** (**3.1.15**) and/or components for hardware (**3.1.22**)

3.1.8 consumer risk profile (CRP)

consideration of the likely risk to consumers of a particular product, part of a product, and/or process, identified by **risk assessment**(s) (**3.1.34**)

3.1.9 contaminant

unwanted and unintended constituent

3.1.10 corrective action

action taken to result in a process improvement to correct an identified problem, in the context of quality and safety management systems

3.1.11 diluent

solvents making up the **base liquid** (**3.1.3**) and used to dilute concentrations of nicotine and/or **flavourings** (**3.1.19**)

NOTE The terms "diluent" and "excipient" have technically different meanings, but for the purposes of this PAS, the term "diluent" is used exclusively.

3.1.12 distributor

any actor in the supply chain whose activity does not affect the **consumer risk profile** (**3.1.8**) of a product

3.1.13 DIY e-liquid kit

equipment sold on the market with which **vaping product** (**3.1.41**) users can mix their own **e-liquid** (**3.1.15**)

*NOTE Typically contains diluted nicotine, **diluents** (3.1.11) and **flavouring** (3.1.19) concentrates.*

3.1.14 electronic cigarette (e-cig)

device which uses electrical power, in combination with an atomizing device and airflow, to generate an inhalable **emission** (**3.1.16**) from **e-liquid** (**3.1.15**)

NOTE 1 An electronic cigarette typically comprises a battery, heating coil and some form of switch.

*NOTE 2 For the purposes of the PAS, the term "electronic cigarette" includes **e-shisha** (3.1.17) products, unless otherwise stated.*

3.1.15 e-liquid

liquid solution(s) which may or may not contain nicotine for use in an **electronic cigarette** (**3.1.14**)

3.1.16 emission

compound produced when a **vaping product** (**3.1.41**) is activated

3.1.17 e-shisha

subset of products which are identical in function to **electronic cigarettes** (**3.1.14**), but are usually marketed as a distinct product, often containing no nicotine and usually fruit-flavoured

NOTE *Also known as shisha sticks, shisha pens and e-hookahs.*

3.1.18 finished product

products to be placed on the market for use by consumers

NOTE *For example pre-mixed **e-liquid** (**3.1.15**) products, and/or **DIY e-liquid** (**3.1.12**) kit products, and/or **hardware** (**3.1.22**) devices.*

3.1.19 flavouring

one or more **flavouring compound**(s) (**3.1.20**) used to add flavour to **e-liquid** (**3.1.15**)

3.1.20 flavouring compound

specific individual chemical substance, extract or natural **ingredient** (**3.1.23**) used to develop **e-liquid** (**3.1.15**) **flavourings** (**3.1.19**)

3.1.21 food grade

flavourings (**3.1.19**) and/or materials achieving the required standards for food safety, as defined by European legislation

3.1.22 hardware

part(s) of a **vaping product** (**3.1.41**) which is neither an **accessory** (**3.1.1**) or an **e-liquid** (**3.1.15**)

3.1.23 ingredient

substances including the diluents, **flavouring compounds** (**3.1.20**) and nicotine (if applicable) used in the formulation of **e-liquid** (**3.1.15**)

3.1.24 manufacturer

entity outside the EU which fabricates VP for import into the EU by **producers** (**3.1.27**) within the EU

NOTE *For the purposes of the PAS, EU manufacturers are described consistently as "producers".*

3.1.25 mod

electronic cigarette (**3.1.14**) which accepts separate batteries or is in other ways user-customizable, and which has a connector to accept an **atomizer** (**3.1.2**)

3.1.26 pre-filled product

type of electronic cigarette device for inhalation of **e-liquid** (**3.1.15**) **vapour** (**3.1.43**) where battery, **atomizer** (**3.1.2**) and **e-liquid** (**3.1.15**) **cartridge** (**3.1.6**) form a composite whole, or where a pre-filled replacement **cartridge** (**3.1.6**) is designed only for use with the original device

NOTE *These are commonly referred to as "1st generation" products, although some products of this type would be considered "2nd generation".*

3.1.27 producer

EU entity which manufactures within the EU, imports into the EU, or brands a product as its own, or the EU representative of a non-EU **manufacturer** (**3.1.24**)

3.1.28 production batch

products created to a specified volume from identified components/base **ingredients** (**3.1.23**) according to the **batch specification** (**3.1.4**)

3.1.29 product recall

recall of product from end users as well as from the supply chain

NOTE *A product recall is usually instigated only when consumer safety is put at risk by the product.*

3.1.30 product withdrawal

product removed from sale across the supply chain

NOTE *Usually a voluntary process, more likely to relate to quality than consumer safety.*

3.1.31 purified water

water that meets the "Ph. Eur. Purified Water 0008" and/or "Purified Water USP" monographs

3.1.32 quality assurance

any systematic process of checking to see whether a product or service being developed is meeting specified requirements

3.1.33 refillable

type of electronic cigarette which has a device for inhalation of **e-liquid** (**3.1.15**) **vapour** (**3.1.43**) which utilizes a **tank** (**3.1.38**) system for holding e-liquid, and which tank can be refilled from provided and/or separately purchased e-liquid

NOTE These are commonly referred to as "2nd and 3rd generation" products.

3.1.34 risk assessment

assessment of the risks presented by a component of **e-liquid** (**3.1.15**) or **hardware** (**3.1.22**), and **finished product**(s) (**3.1.18**)

NOTE This term relates to both toxicological and other types of risk.

3.1.35 risk-based compliance check

check on the compliance of products whose range, depth and frequency are proportionate to the risk of non-compliance, as determined by the **producer** (**3.1.27**) in consultation with regulators

NOTE Where no checks have previously been carried out, this risk will be high, and the checks will reflect this. Over time, as checks are carried out, and conformity with product specifications is determined, this risk might reduce and with it, the checks that are carried out.

3.1.36 shelf life

period during which products are predicted to remain within specification

3.1.37 substantial modification

material change(s) to a product specification which increases the **consumer risk profile** (**3.1.8**).

*NOTE This can include, for example, relevant changes to the quantity of **ingredients** (**3.1.23**), use of different ingredients, or substantial changes to the device design. It is unlikely, for example, to include minor changes such as sourcing a **vapour** (**3.1.43**) product component or **ingredient** (**3.1.23**) of the same specification from a different supplier.*

3.1.38 tank

reservoir for holding **e-liquid** (**3.1.15**) and supplying it to the **atomizer** (**3.1.2**) by means of a **wick** (**3.1.44**)

3.1.39 toxicological risk assessment (TRA)

process by which competent toxicologists evaluate the potential for adverse health effects from intended use and foreseeable accidental exposures from a **vaping product** (**3.1.40**)

3.1.40 vaping

inhalation and exhalation of the **vapour** (**3.1.43**) produced by the activation of an **electronic cigarette** (**3.1.14**)

3.1.41 vaping product (VP)

product, and/or part of product, which is used within a device designed to produce **vapour** (**3.1.43**) for inhalation, and which may or may not contain nicotine

*NOTE Includes **electronic cigarettes** (**3.1.14**), **e-shisha** (**3.1.16**) products, e-liquids (3.1.4), mixing kits, **mods** (**3.1.24**), batteries, and all other products and accessories which are sold for the purpose of **vaping** (**3.1.40**).*

3.1.42 vaping product without nicotine (VPWN)

product, and/or part of product, which is used to produce **vapour** (**3.1.43**) for inhalation, and which contains nicotine at a concentration of less than 0.01% w/v (i.e. less than 0.1mg/ml)

3.1.43 vapour

emission(s) (**3.1.16**) produced by activation of an **electronic cigarette** (**3.1.14**)

*NOTE Technically, the **emissions** (**3.1.16**) are an aerosol consisting of both gas and liquid phase components.*

3.1.44 wick

material used to draw **e-liquid** (**3.1.15**) to the **atomizer** (**3.1.2**) for vapourization

3.2 Abbreviations

For the purposes of this PAS, the following abbreviations apply.

CE	*Conformité Européenne*, comprising the Electromagnetic Compatibility Directive [3] and the Low Voltage Directive [2]
CLP	Classification, Labelling and Packaging Regulation (EC) No. 1272/2008 [5]
CMR(s)	substances which have carcinogenic, mutagenic, and/or reproductive toxicity
CRP	consumer risk profile
e-cig(s)	electronic cigarette(s)
ELP	e-liquid producer
FEFO	first expired/first out
FIFO	first in/first out
FS	flavouring supplier
FSA	Food Standards Agency
GC/MS	gas chromatography/mass spectrometry
GHS	globally harmonized system of classification
GPSD	General Product Safety Directive 2001/83 [1]
GMP	good manufacturing practice
HACCP	hazard analysis and critical control point
mAh	milliampere-hour
MSDS	material safety data sheet
PG	propylene glycol
Ph. Eur./USP	European Pharmacopoeia or United States Pharmacopeia standard
PPE	personal protective equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation EC No. 1907/2006 [6]
RoHS	Restriction of Hazardous Substances Directive 2011/65 [4]
RS	respiratory sensitizers
THR	tobacco harm reduction
TPD	Tobacco Products Directive 2014/40 [11]
TRA	toxicological risk assessment
TSNA	tobacco-specific nitrosamine
UBR	unique batch reference
VP	vaping products
VPWN	vaping product without nicotine
(W)EEE	(waste) electrical and electronic equipment
w/v	weight for volume
w/w	weight for weight

4 E-liquids

*NOTE The principles behind the guidance in this clause apply to the hardware as well. Therefore Clause **5** makes reference back to this Clause.*

4.1 Manufacturing facilities

Even though micro-organisms are not likely to grow in nicotine-based solutions, precautions should be taken for both nicotine containing products and VPWNs to ensure that any microbial contamination is minimized during handling and/or processing of the ingredients during formulation of e-liquid products.

NOTE 1 Particular attention is drawn to the principles of hazard analysis and critical control points (HACCP). The EU has published some guidance on the principles and implementation of HACCP: Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs *[21].*

Although VP are not classified as foods, the principles behind good manufacturing practice as it is applied in the food industry provide a useful frame of reference and should be applied.

NOTE 2 This ensures a high standard of hygiene with the potential for microbial contamination to be minimized through a robust audited and certified quality system.

NOTE 3 Using pharmaceutical grade in-going ingredients is not sufficient to claim pharmaceutical grade e-liquid as this involves manufacturing being performed under accredited pharmaceutical good manufacturing (GMP).

4.2 Personal Protective Equipment (PPE)

PPE should be provided for all staff working in e-liquid manufacturing facilities, according to the process being undertaken and the risks as assessed. PPE protects the product from the staff, as well as the staff from the product.

NOTE 1 Attention is drawn to requirements in the Control of Substances Hazardous to Health Regulations (2002) [14], the Personal Protective Equipment Regulations (2002) [15], the Health and Safety (First-Aid) Regulations (1981) [16] and the Health and Safety (At Work) Act (1974) [17] concerning protection of staff in the work environment, such as the provision of first aid kits, eye wash centres, spill kits, etc., and engineering controls.

NOTE 2 Attention is also drawn to the requirements for hygiene detailed in Food Standards Agency (FSA) recommendations at www.food.gov.uk/business-industry/guidancenotes/hygguid/fsactguide.

4.3 Process control

4.3.1 General

To produce predictably consistent VP, the production process should be defined, controlled and documented to ensure that VP meet their product specification.

NOTE 1 If the raw materials, previously processed materials, and/or other components (collectively the "input") entering the process, or the process itself, introduce too many variables, the products of the process are unlikely to meet their product specification.

Product specifications, batch specifications, process monitoring, product testing, manufacturing site cleaning, and other quality control measures should be documented. Such documentation should be internally audited and made available to enforcement officers on request or at least within seven days of such request being made.

Documented process monitoring and control should be in place so that in the event that a problem is identified, it can be determined whether it is a one-off, limited to a specific production batch, or spanning across traceable batches.

Where processes are interlocked, i.e. where one process is dependent on another, a clear documented end point should exist for each process, with defined quality control to ensure that any errors made are not carried over into subsequent processes.

Where problems have been identified, this should inform the process monitoring and control documentation to reduce the likelihood of similar problems occurring.

NOTE 2 If the input is highly variable, no amount of control during the process will achieve a consistent output.

NOTE 3 An example of the process for the production of a batch of flavoured e-liquid is provided in Figure 1.

Control of a process should be managed by a competent person (i.e. someone with a sufficiently high level of training, experience and knowledge, and

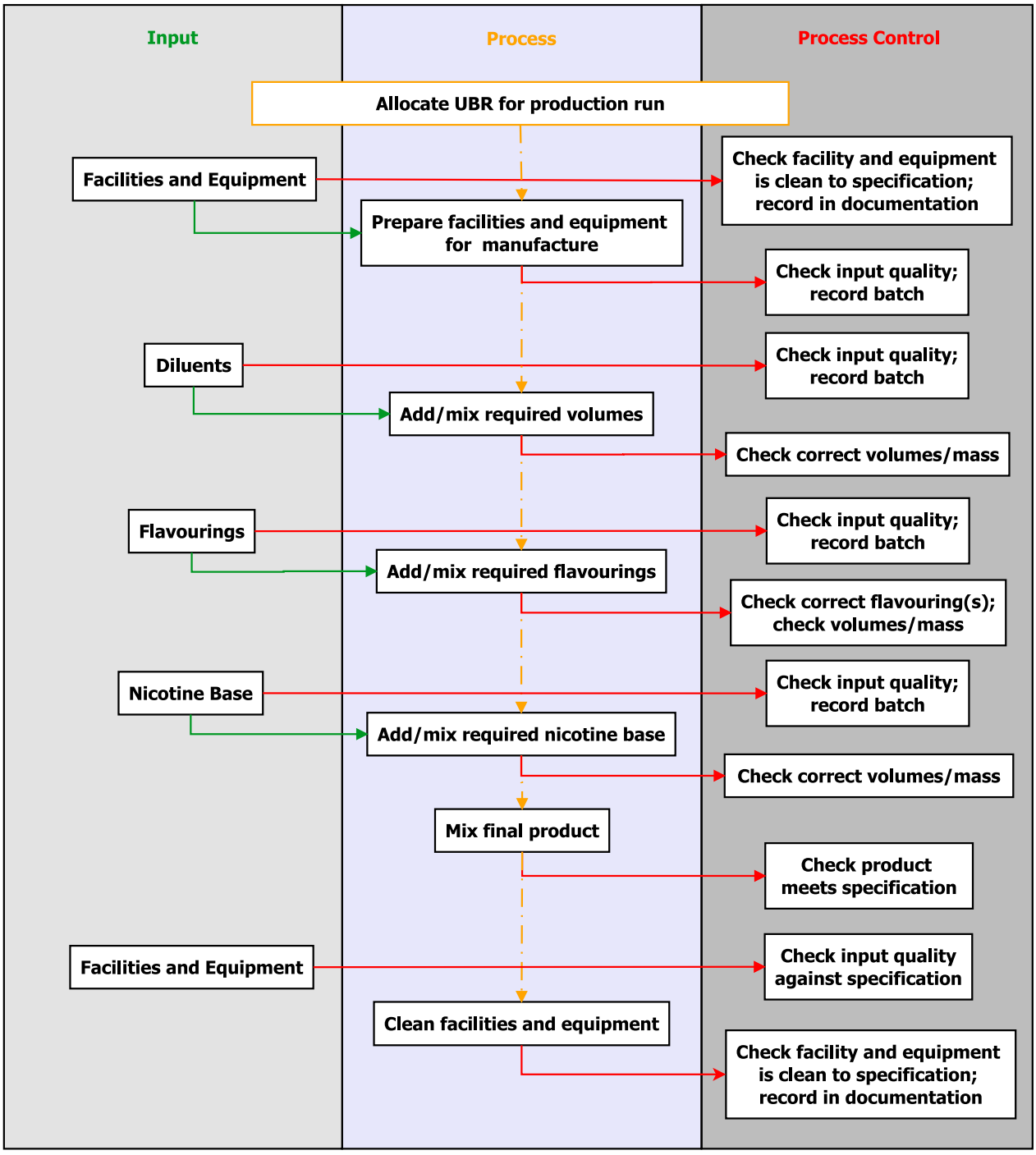
who is entrusted with the authority to sign the process control documentation on behalf of the company) with a practical understanding of the process, in co-operation with the staff performing that process, who should themselves be appropriately trained to be able to execute their functions to a satisfactory level.

The process should be documented so that all those involved in it have a clear understanding of their role, and to identify the points at which to implement quality control checks.

Such documentation should include the inputs required for the process, the detailed procedures forming the process, and the desired result of the process, i.e. referring to the product specification(s).

Quality assurance measures should be taken on the materials forming the input of the process. These will vary depending on the product and process in question, but should ascertain that the input materials are suitable to meet the product specification.

Figure 1 – Example process for the production of a batch of flavoured e-liquid



Documentation should be kept for all production and quality assurance steps, so that if a problem is identified with the output from a process, this can inform changes to the quality assurance, staff training or the process itself.

4.3.2 Product specifications

As the first step in establishing control of a process, a detailed specification should be created that defines the final product.

The exact nature of the specification will depend on the exact nature of the vaping product in question, but for example, for production of a batch of flavoured e-liquid, the product specification should cover the total volume of the batch, the concentration and quality of individual diluents, the concentration and quality of each flavouring, and the concentration and quality of nicotine.

The product specification should include a release specification (a list of product attributes defined by the producer, against which all batches of manufactured product should be checked and recorded).

The product specification should also include a shelf life specification. There should be a clear shelf life established for the product, with supporting documentation to demonstrate how this was decided. The shelf life specification should be based on stability data (generated by persons qualified to undertake such testing) and risk assessment of likely conditions, such as during transportation, particularly if international. In establishing the various parts of the overall product specification, consideration should be given to the formulation of the product and the significance of the content necessary for each component to achieve a satisfactory product.

Risk-based compliance checks should be undertaken to ensure that vaping products remain within specification throughout their shelf life, with supporting documentation filed in the technical dossier (see **4.7**). The risk profile may change depending on the results of the on-going checks.

Risk assessments should be reviewed on a regular basis (e.g. monthly, annually, bi-annually, etc.,) depending on risk, or if something changes, e.g. a new worker, a change of process or substance, etc. The results of reviewed risk assessments should inform the frequency of compliance checks on both products and processes.

The methods of checking products should be defined, validated and form part of the specifications.

Appropriate tolerance values should be established and justified in the supporting documentation for all measurements in the product specification.

4.4 Batch traceability

To ensure full traceability of batches, the supplier's batch number(s) and supplier's details for all ingredients/components used in the manufacture of an importer's/producer's batch, and for how long batches were mixed (to ensure that mixing is completed in a consistent and reproducible way) should be logged, together with the serial number(s) of the production equipment used, if present, and the batch number assigned to the final vaping product following manufacture.

Such records should be maintained and kept for one year after expiry of the batch to which it relates, or a minimum period of 3 years from the first date of production, whichever is the longer.

NOTE 1 *See Table 1 for sample batch record and Figure 2 for a batch traceability model.*

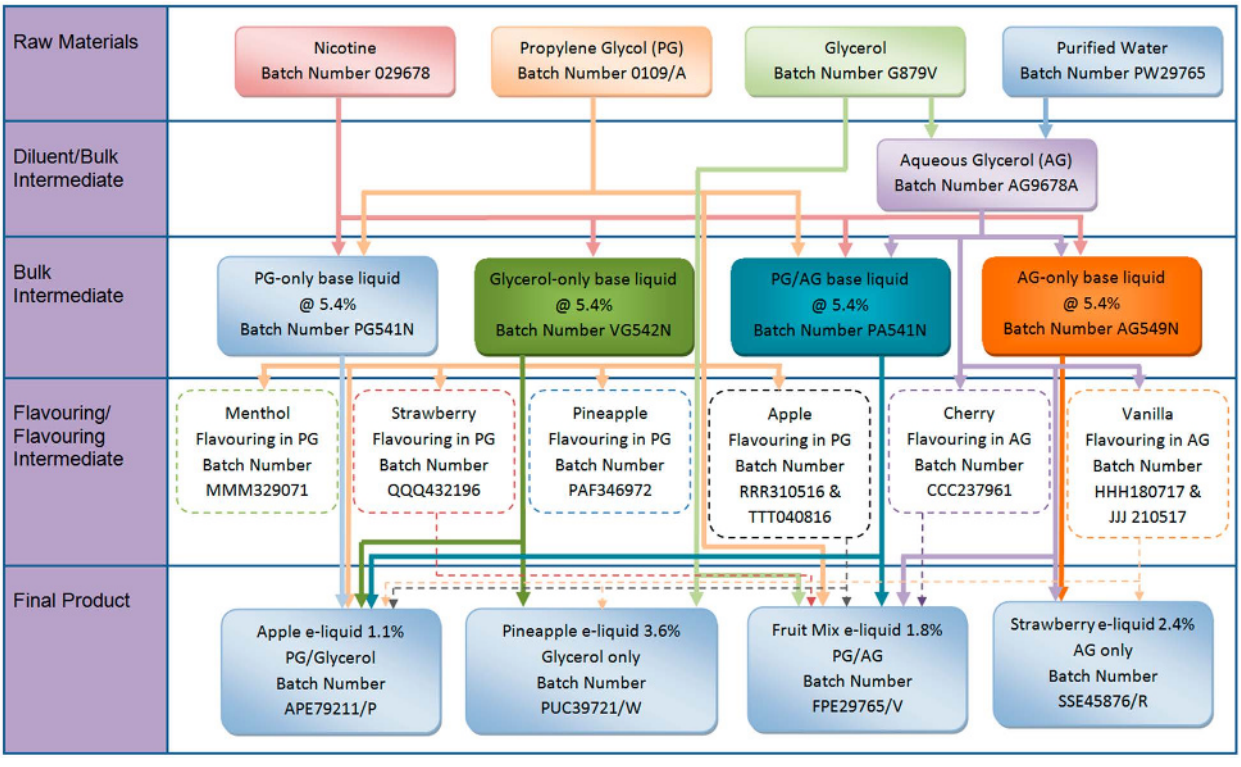
NOTE 2 *If a problem with a vaping product is identified after sale, maintenance of these records will enable the identification of affected batches allowing for effective corrective action measures.*

NOTE 3 *Traceability of ingredients – within a framework of regular, risk-based assessments – considerably reduces the negative impact of corrective action procedures while ensuring a high level of consumer protection. See Annex A for a worked example of the batch traceability model.*

Table 1 – Sample batch record

Sample batch record						
Product name			UBR			
Facility check				**By operator**	**Checked by**	**Date**
Component process	**Component UBR**	**Quantity required**	**Quantity added**	**By operator**	**Checked by**	**Date**
Batch approved by						
Name			Sign		Date	

Figure 2 – Batch traceability model



4.5 Corrective actions

4.5.1 General

A risk assessment of the vaping product should be undertaken.

NOTE 1 *Attention is drawn to CENELEC Guide 32* Guidelines for safety related risk assessment and risk reduction for low voltage equipment *[22].*

NOTE 2 *Attention is also drawn to the European guidance document* Product Safety in Europe: A Guide to corrective action including recalls *[23].*

The severity of any problem identified dictates which type of corrective action may be undertaken.

NOTE 3 *ttention is drawn to the requirements for products to be as described and fit for purpose under the Sale of Goods Act 1979 [24] and the Consumer Protection from Unfair Trading Regulations 2008 [25].*

If a corrective action is required for any reason, an investigation should be undertaken to establish the cause of the problem. Procedures should be checked and improved as dictated by the outcome of the investigation, to minimize the risk of a repeat of such failures, with documentation supporting that the necessary procedures have been introduced or modified. Such procedures may include, but are not limited to:

a) verifying the supporting documentation accompanying raw ingredients;
b) liaising with up-stream suppliers to establish the source of any contamination;
c) checking the manufacturing facilities for contamination entry points;
d) ensuring that such entry points are repaired/ replaced to ensure that no further contamination can enter the production process.

4.5.2 Product recalls

Batches for which the residual level of risk is not supportable, i.e. batches for which problems liable to adversely affect user health, safety or well-being have been identified, e.g. as part of a toxicological risk assessment or other analysis, should be recalled from sale across the whole supply chain. These batches should also be recalled from consumers who have purchased them. Such problems with batches may be identified by routine assessments and analyses carried out by the producer, and/or by customer complaints, and/or by enforcement activities by government agents, and/or by other means.

VP with problems which do not affect safety, for example, misformulation of flavour by omitting a flavour compound, or a device having an unusually short working life, might still result in product withdrawal or recall for non-safety reasons, at the producer's discretion.

Product recall procedures should be formulated to ensure that any product which has been sold either to resellers or to the public, for which problems have been identified, can be effectively recalled from sale across the whole supply chain. Where such problems affect safety, the appropriate authority should be notified.

NOTE 1 *An example of an appropriate authority is Trading Standards.*

Resellers all the way through the supply chain should be informed as soon as is practically possible if a product recall is instigated. Documentary evidence should support any such action, including confirmations received from every part of the supply chain involved, with such evidence made available to regulators on request, or at least within seven days of such request being made. If a recall is instigated, relevant authorities should be notified as soon as practically possible and such information made available to them as required.

NOTE 2 *Attention is drawn to notification obligations in the General Product Safety Directive 2001/83 (GPSD) [1] and the Tobacco Products Directive 2014/40(TPD) [11].*

NOTE 3 *See Annex A for a worked example of identifying finished product batches for recall via the batch traceability model.*

4.5.3 Product withdrawals

VP in which problems have been identified which the risk assessment confirms do not pose a risk to the health, safety and well-being of consumers can be withdrawn from sale across the supply chain at the producer's discretion.

Even in the case of product withdrawals, producers should still ensure that clear procedures are in place and are followed, to ensure full communication of the producer's decision across the supply chain, together with the rationale for the decision to withdraw the product.

Documentary evidence should support product withdrawals, including confirmations received from every part of the supply chain involved.

NOTE *Attention is drawn to notification obligations in the GPSD [1] and the TPD [11].*

4.6 Ingredients

4.6.1 Storage requirements

All ingredients should be stored, maintained and documented according to a first in/first out (FIFO) and/or first expired/first out (FEFO) system. It is important that an ingredient rotation system is in operation so that expired stock is not used.

4.6.2 Undiluted nicotine

Nicotine should be of European Pharmacopoeia/United States Pharmacopoeia Standard (Ph. Eur./USP) grade, with accompanying documentation supporting this standard, including a certificate of analysis and/or certificate of conformity, and should have a unique batch reference (UBR).

NOTE *Undiluted nicotine is highly toxic, so companies handling pure nicotine are required to hold a Poisons License, under the Control of Poisons and Explosives Precursors Regulations 2015 [12], and the Poisons Act 1972, as amended [13].*

Attention is drawn to the very strict requirements of health and safety legislation, such as Control of Substances Hazardous to Health Regulations 2002 [14], Personal Protective Equipment Regulations 2002 [15], the Health and Safety (First-Aid) Regulations 198) [16] and the Health and Safety (At Work) Act 1974 [17] for working with dangerous chemicals.

4.6.3 Prediluted nicotine

Both the nicotine and the diluent should be of Ph. Eur./USP grade, with accompanying documentation supporting this standard for all ingredients, including certificate(s) of analysis and/or certificate(s) of conformity.

The prediluted nicotine product should itself have a UBR.

NOTE *Nicotine supplied below 7.5% w/w concentration in solution of diluent is exempted from the Control of Poisons and Explosives Precursors Regulations 2015 [12], so that a Poisons Licence is not required.*

4.6.4 Diluents

Diluents purchased for the manufacture of e-liquid should be of Ph. Eur./USP grade. Water used as a diluent should be purified water that meets the "Ph. Eur. Purified Water 0008"/"Purified Water USP" monographs. They should be supplied with accompanying documentation supporting this grade for any such ingredients, including certificate(s) of analysis and/or certificate(s) of conformity. Di-ethylene glycol is a potential contaminant for propylene glycol and glycerol.

Ph. Eur. propylene glycol should be tested to ensure that the level of di-ethylene glycol does not exceed 0.1%.

NOTE *Testing for this at the input stage will assist with reducing the frequency of risk-based compliance checks. The specification of USP propylene glycol and Ph. Eur. and USP glycerol already includes a requirement that they contain no more than 0.1% di-ethylene glycol, therefore no separate testing on this aspect is required for these diluents.*

Each diluent should be supplied with its own UBR, and producers should ensure that UBRs for their own e-liquids can be traced all the way back to the initial input materials.

4.6.5 Nicotine concentration assay

Once the producer has created the base liquid to the desired nicotine content, this should be verified to ensure that e-liquids manufactured from this base liquid contain the nicotine concentration defined in the product specification.

The assay should be documented, with such documentation included in the technical dossier (see **4.10.4** below for concentration limits).

Titration is the most accessible and cheapest method for in-house nicotine assay (although other methods will provide better precision). It is capable of providing an internal check on dilution of nicotine for production of stock solutions or input materials, but the end product should be checked using a justifiably precise analytical method, such as HPLC, GC/FID or isotope dilution analysis, to confirm that the process is able to deliver accurate nicotine concentrations.

4.6.6 Flavourings

Flavouring ingredients are usually supplied in diluent. The diluents used for these products should be of Ph. Eur./USP grade where available in that grade, or be of food grade, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity.

These flavouring products should have a UBR which ensures traceability to raw ingredients, and which can be incorporated into the producer's UBR for its own e-liquid product.

All flavourings, whether natural or artificial, should be of food grade, with the exception of flavourings extracted from tobacco (tobacco extracts). All flavourings including natural extracts should be considered in the product's toxicological risk assessment (TRA), where a TRA is deemed necessary (see **4.8**), and removed from the manufacturing process if a problem is identified by the TRA.

In the case of tobacco extracts, additional analyses should be undertaken to ensure that tobacco-specific nitrosamines (TSNAs) are measured and reduced to toxicologically supportable levels.

Final measurements of TSNAs in tobacco extracts for use as inputs for production of e-liquids should be recorded and filed in the technical dossier.

If adverse reactions are reported for any flavourings, they should be investigated. The TRA for the causative components should be updated with the new information. If the substance or extract is no longer toxicologically supportable for use in e-liquid, it should be added to the list of substances which should not be added to or present in e-liquid (see Table 2). Each producer should maintain such a list, and where possible, these should be harmonized with other producers to maximize consumer protection.

At the time of publication there is no centralized body to co-ordinate this harmonization, however, if one becomes available, this should be used by each producer. Until such time, producers and distributors should submit data on adverse reactions and ingredients that are no longer toxicologically supportable for use in e-liquid to their local Trading Standards officer, so that this information can be centrally shared.

NOTE *One practical risk management measure is to use only artificial flavours and mixtures. Natural flavours often have a complex and variable composition so their use is therefore associated with more uncertainty and this will need to be taken into account by a TRA.*

4.6.7 Additional ingredients

Any additional ingredients should be subject to TRA, which will determine whether or not they are acceptable for use in the e-liquid.

4.6.8 Substances which should be controlled in e-liquids

The ingredients which should not be added to e-liquids are listed in Table 2. If these compounds are identified during testing, the affected e-liquids should be withdrawn and/or recalled from sale. depending on the level of risk they present, as described at **4.5.2** and **4.5.3** above. Producers should examine their processes to establish how such contaminants were introduced (see **4.5**).

Producers should examine their processes to establish how such contaminants were introduced, which might result in corrective actions (see **4.5**).

NOTE 1 *Under certain jurisdictions (i.e. EU proposals under the TPD [11]) ingredient reporting is legally required and provides an established mechanism to inform competent authorities.*

NOTE 2 *Attention is also drawn to the potential for ingredient regulations to be in place in the country of sale.*

Table 2 – List of substances which should be controlled in e-liquid

Substance	Recommendations
Carcinogenic, mutagenic and/or reproductive toxicants (CMRs)	E-liquids should not contain any ingredients that have been classified as carcinogenic to humans, mutagenic or toxic to reproduction. ***NOTE*** *Attention is drawn to CLP where nicotine is not classed as a CMR.*
Respiratory sensitizers	Any substance which is classified as a respiratory sensitizer should not be added to e-liquids. ***NOTE*** *Attention is drawn to CLP [5] and REACH [6].*
Diacetyl (CAS 431-03-8) and pentane 2,3 dione, CAS 600-14-6	Producers should refer to the regulatory and scientific literature on permissible exposure levels. ***NOTE*** *Attention is drawn to the 'European Commission Scientific Committee on Exposure Limits (SCOEL) "Recommendation from the Scientific Committee on Exposure Limits for Diacetyl. SCOEL/SUM/149", .2014, http://ec.europa.eu/social/BlobServlet?docId=6511&langId=en* Butane 2,3 dione and pentane 2,3 dione have known inhalation risks and should not be used in flavourings.
Diethylene glycol (CAS 111-46-6) Ethylene glycol (CAS 107-21-1)	These should not be added as ingredients to e-liquids butmight be present as contaminants in in-going glycerol and propylene glycol at a maximum level of 0.1% (see **4.6.4**). They should not be introduced to e-liquids through flavouring diluents or other processes.
Formaldehyde (CAS 50-00-0), acetaldehyde (CAS 75-07-0), and acrolein (CAS 107-08-8)	These should not be added as ingredients to e-liquids but might be present. If they are present, they should not be present above toxicologically supportable levels levels (as identified by the TRA). As formaldehyde is an ubiquitous chemical, a control measurement should be taken before commencing the test, to ensure that environmentally- and/or human-produced formaldehyde is not incorrectly attributed to the product test results.
Metals, to include cadmium (CAS 7440-43-9), chromium (CAS 7440-47-3), iron (CAS 7439-89-6), lead (CAS 7439-92-1), mercury (CAS 7439-97-6), and nickel (CAS 7440-02-0)	Metals should not be added to e-liquids as ingredients but might be present. If they are present, they should not be present above toxicologically supportable levels (as identified by TRA).

If a TRA identifies a compound of concern for inhalation, this should be reported to a competent authority, such as Trading Standards. In this way, additional compounds can be added to the list of substances which should not be added to the products, so that other producers can be informed.

NOTE 3 *Attention is drawn to the definition of a "safe" product in the GPSD [1].*

NOTE 4 *Attention is also drawn to the additional prohibitions proposed in Article 20 of the TPD [11], although this is subject to Judicial Review by the European Court of Justice.*

4.6.9 Technical dossier

A technical dossier should be produced and maintained by the producer and approved by the competent person/authorized representative of the company for each e-liquid, flavouring concentrate and/or base liquid product manufactured.

Recent testing reports of the regular batch testing of specific e-liquid, flavouring concentrate and/or base liquid product recipes should be filed in the technical dossier.

The technical dossier should contain the following elements, where applicable to the type of vaping product:

a) contact details for authorized representative of producer, including physical address, telephone contact number and email address;
b) general description of the product;
c) product specification;
d) product development and stability data;
e) list of ingredients/components used in the formulation/manufacture of the product, with batch analytical data and batch records;
f) copies of risk assessments;
g) manufacturing process description and validation;
h) copies of certifications for manufacturing facilities and product ingredients (where applicable);
i) copies of all test reports relevant to the quality and safety of the marketed product, potentially including nicotine assay(s), post-production analyses, including stability/shelf life data, electrical safety, etc. (where applicable);
j) copies of child-resistant packaging checks;
k) copies of any/all TRAs relating to the specific product (see **4.8**);
l) copy of product label/packaging design;
m) copy of the instructions for use and product information, if applicable;
n) records of customer complaints and/or reports of adverse events relating to the product, if they relate to product safety;
o) documentary evidence of corrective actions taken;

The technical dossier should be kept by the producer for a minimum period of 10 years from the date of manufacture.

The technical dossier should be made available to regulatory officers immediately on request, or at least within seven days of such request being made, unless otherwise justified.

NOTE *Importers are defined in law as producers if they import the products from outside the EU into their home market.*

4.7 Toxicological risk assessment (TRA)

A toxicological risk assessment (TRA) should be undertaken on the basis of the on-going risk-based compliance checks, if justified by some form of novelty or anticipated risk.

NOTE 1 *Scientific evidence to date indicates that there is a relatively low risk from electronic cigarette products compared to smoking of tobacco cigarettes. See e.g. Hajek, P., Etter, J.-F., Benowitz, N., Eissenberg, T. and McRobbie, H.,* Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit *[26], Nutt, D. J., Phillips, L. D. Balfour, D., Curran, H. V., Dockrell, M., Foulds, J., Fagerstrom, K., Letlape, K., Milton, A, Polosa, R., Ramsey, J. and Sweanor, D.,* Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach *[27].*

If justified by some form of novelty or anticipated risk, a TRA should be carried out by a competent, qualified and registered toxicology specialist taking into account hazard assessments on every ingredient used in the manufacture of e-liquids, and every component used in the manufacture of hardware, as well as the operating temperatures for both.

TRAs should be undertaken by toxicologists registered with the UK Register of Toxicologists and/or the EUROTOX Register.

A TRA should include four elements:

a) hazard identification of the individual compounds the consumer is exposed to, such as the e-liquid ingredients, leachables from the device materials and their degradation and reaction products;
b) dose-response information on those compounds, determining how much effect a certain exposure

would cause and identifying if there is an exposure level at which risk is likely to be negligible or acceptable/tolerable based on comparability to other exposure benchmarks, using appropriate safety factors.

NOTE 2 *Other exposure benchmarks can include tobacco cigarettes, nicotine replacement products, occupational exposures, food and environmental exposures.*

a) exposure assessment, identifying how much of the compound consumers might be exposed to from the intended use and foreseeable accidental exposures;
b) risk characterization, integrating the pertinent information from the preceding steps to characterize the risks to the user. At this stage, the potential for cumulative effects from the different compound(s) is accounted for. A toxicological risk assessment specifies what the assumptions and uncertainties were that went into the risk assessment.

A TRA should compare the estimated levels of consumer exposure to relevant benchmarks, e.g. cigarette smoke, environmental, workplace exposure levels, acceptable daily intakes, etc.

NOTE 3 *Consumer exposure is determined based on knowledge of the way the product is used, as well as knowledge of the e-liquid ingredients, the materials used in the manufacture of the e-cigarette, combined with the analytical data obtained on the e-liquid and emissions.*

The TRA should include both normal use and foreseeable accidental or deliberate exposure scenarios. For pre-filled vaping products, the TRA should also cover device leachables and thermal degradation products, including those specified in **5.6**.

Leachables and thermal degradation products produced by mods and refillables may be tested as per Annex B, using a test solution. If the product instructions make any recommendations on compatible e-liquid composition(s), then testing should use the e-liquid(s) mentioned. Otherwise, the test e-liquid described at **5.5** should be used. Deviations should be justified and documented on the basis of device compatibility or documented consumer use conditions.

Where e-liquids are sold separate from devices, likely thermal degradation can be measured using a commercially available refillable e-cigarette or other test device, the choice of which should be justified and documented.

Toxicological information for individual ingredients and aerosol contaminants can be adjusted for the exposure expected from a specific product and then combined in an overall product TRA. The overall product TRA should assess any restrictions resulting from the co-exposure of compounds that result in similar adverse effects.

In the case of flavourings, the flavouring compounds present in the e-liquid should be known from supplier's disclosure information or be identified by means of analytical assessment. The TRA can be produced for each of the flavouring compounds identified.

NOTE 4 *It is not necessary to repeat steps a) and b) of the TRA for the same flavouring compound or other ingredient, so information can be reused across a wide range of e-liquid products which all use the same ingredients and/or flavouring compounds.*

NOTE 5 *Attention is drawn to producers' obligations under the GPSD [1].*

4.8 Substantial modification

If a producer substantially modifies an e-liquid product, i.e. toxicologically significant increases of ingredient levels (as determined by a competent toxicologist), new flavour compounds are introduced, nicotine concentration is altered by ± 15% from the original value, or any other modification is made which will alter the consumer risk profile (CRP), then a new technical dossier should be produced for the modified product.

4.9 E-liquid testing

4.9.1 General

E-liquids should be regularly monitored to ensure that the nicotine content is as specified, and that any contaminants are minimized. This monitoring should also ensure that manufacturing specifications are being adhered to and that no contamination is occurring during the manufacturing process (see Table 2). Either building up separate components (as per **4.9.4**), or by finished product testing, e-liquids should be tested by quantitative analysis for potential contaminants and nicotine concentration to ensure that they meet the product specification. The risk based compliance checks schedule should take into account the risk of contamination being introduced during the production process of each batch.

NOTE 1 *Robust and proportionate testing can also help encourage innovation and the widest possible offering of choices to consumers.*

NOTE 2 *Testing is an important part of ensuring that producers are only placing products on the market of appropriate safety and quality. The frequency and type of testing required will depend on the type of product, and the producer's risk based compliance checks.*

Distributors who are reselling a manufacturer's e-liquid product should obtain the quality assurance documentation from the manufacturers for their technical dossier. If the manufacturers cannot provide adequate testing documentation, the distributor should test, or arrange for the testing, as described at **4.10.1**.

Risk-based compliance checks for conformity with the product specification should be undertaken as given in this PAS, with corrective actions (where taken) documented and included in the technical dossier. While ultimately risk based conformity checks should be decided by the producer, at a minimum, this should cover the first three commercial batches and include at least one batch for each e-liquid, flavouring concentrate and/or base liquid product per year.

4.9.2 Base liquids

Nicotine and diluents should enter the manufacturing process with certificates of analysis and/or conformity from the original supplier, demonstrating that these raw ingredient products meet the required pharmaceutical grade. When the base liquid is manufactured, for use in the wider range of e-liquids, providing the titration (or other appropriate) analysis (see **4.6.5**) is carried out, there is no need to test for contaminants at this stage in the process. Di-ethylene glycol is a potential contaminant for propylene glycol, and glycerol, so testing (or requiring that upstream suppliers test) for these at the input stage will assist with reducing the frequency of risk based compliance checks.

4.9.3 Flavour concentrates

All flavourings and/or concentrates, except tobacco extract flavouring, should enter the manufacturing process with certification from the original supplier, confirming food grade purity.

Tobacco extract flavouring should enter the manufacturing process with certification confirming the level of any potential substances of toxicological concern, such as TSNAs, to inform the final product TRA. This certification should form part of the technical dossier, and should be directly referred to as part of the documented checks of inputs to production processes.

Distributors should request all such documentation from their suppliers, in order to meet their own due diligence obligations.

NOTE 1 *Attention is drawn to the GPSD [1].*

NOTE 2 *If all base ingredients, i.e. nicotine, diluents and flavourings are tested at this early stage, this may have a significant impact on reducing the amount of testing required on finished product.*

4.9.4 Pre-mixed e-liquids

If base ingredients have been tested as per **4.9.1**, **4.9.2** and **4.9.3**, and producers hold the documentation in support of such testing, it will only be necessary to establish a monitoring system and test a representative set of finished products where sampling size and method are dictated by the producer's risk based compliance check schedule.

A VPWN should be tested as well as some e-liquids with nicotine, to ensure that e-liquids labelled as containing no nicotine are accurately described, and that nicotine contents are also accurately described. For e-liquids that are not intended to contain nicotine, the concentration of nicotine should be less than 0.01% w/v.

The quantitative analyses for finished products should demonstrate that nicotine concentrations are accurate to within ± 10% of label claim for nicotine concentration for liquid products (sold in bottles), and within ± 20% of label claim for pre-filled products for the duration of their respective shelf lives. In the case of VPWN, the nicotine tolerance clearly does not apply.

NOTE 1 *These tolerable variation limits are in place to allow for some degradation of nicotine (and hence a reduction in its concentration) over time.*

NOTE 2 *stablishing the concentration of nicotine will have to take into account the accuracy and precision of the analytical method, hence the recommendation to use quantitative analysis at **4.9.1**.*

If base ingredients have not been previously tested, in the first instance, producers and/or distributors should ask their suppliers to carry out such testing, and supply the documentary evidence in support. If suppliers appear unwilling or unable to provide such evidence, producers and/or distributors should undertake such testing across the e-liquids in their ranges.

All e-liquid products placed on the market should first have been subject to quantitative and qualitative analyses to ensure that due diligence obligations have been met.

NOTE 3 *Attention is drawn to the GPSD [1] and the due diligence obligations therein.*

4.9.5 Emissions

The emissions from e-liquids should be tested as proportionate to and justified by a documented risk-based compliance check for the production of inhalation toxicants produced during the vapourization process.

Emissions measured may be limited to those from a representative e-liquid of the product range if a scientific justification can be provided for read-across of the results to related e-liquids of the same range.

Where e-liquids are sold separate from devices, their emissions can be measured using a commercially available refillable e-cigarette or other test device, the choice of which should be justified and documented.

New emissions testing should be undertaken when there are substantial modifications in base liquids and/or substantial additions of new flavourings.

If toxicants are generated by an e-liquid at levels that are not toxicologically supportable by a TRA, where a TRA is deemed necessary, the affected e-liquids should not be sold, and e-liquid recipes should be reformulated to reduce such components to a level that can be justified by a TRA.

This testing should be carried out by qualitative and quantitative analysis, and the results evaluated by TRA.

Nicotine delivery to vapour should be measured and expressed as mass per puff. Multiple measures of nicotine delivered to vapour by products from different batches can be used to indicate consistent delivery of nicotine across batches (see **5.5** and Annex B).

NOTE 1 *See Annex B for information on compounds to measure in the emissions.*

Emissions testing may be carried out only once for each e-liquid product, unless the e-liquid is subject to a substantial modification. Otherwise, it is reasonable to assume that the emissions will be sufficiently consistent since, provided the formulation is unchanged, the concentrations of chemical species in the liquid (and, hence, the emissions) will be the same.

NOTE 2 *This testing will enable producers to ensure that their e-liquid products are not producing by-products during the heating process when vapourized which pose an inhalation risk to consumers. Since there are producers of both hardware only and e-liquids only, it would be practically impossible to suggest that every e-liquid should be tested in every possible device.*

5 Hardware

5.1 General

All components used in the manufacturing process should be traceable (see **4.4**) so that if a problem is identified in subsequent testing, the problem material may be removed from the specific affected product lines (see **4.5**).

NOTE *Traceability of components, or materials used to make components, considerably reduces the negative impact of corrective action procedures while ensuring a high level of consumer protection, as well as ensuring that international obligations concerning hazardous wasteare complied with. – attention is drawn to Restriction of Hazardous Substances Directive (RoHS) [4].*

5.2 Technical dossiers

A technical dossier should be produced and maintained by the producer for each model or variant of atomizer and/or hardware product manufactured.

To maintain the technical dossier, recent testing reports of the testing of specific product models should be filed in the technical dossier.

For each product model, testing should be undertaken and repeated as indicated by risk-based compliance checks (see **5.5** and **5.6**).

The technical dossier should contain at the least the information identified in **4.6.9**.

The technical dossier should be kept by the producer for a minimum period of 10 years from the date of manufacture of the hardware product.

It should be made available to regulatory officers on request, or at least within seven days of such request being made, unless otherwise justified.

NOTE 1 *Attention is drawn to CE, comprising the Low Voltage Directive [2] and Electromagnetic Compatibility Directive [3], and RoHS [4] documentation requirements, as well as WEEE [7] and the Batteries Directive. [8] For devices that include wireless capabilities such as Bluetooth or w-fi, attention is drawn to the Radio and telecommunications Directive 199/5 [9].*

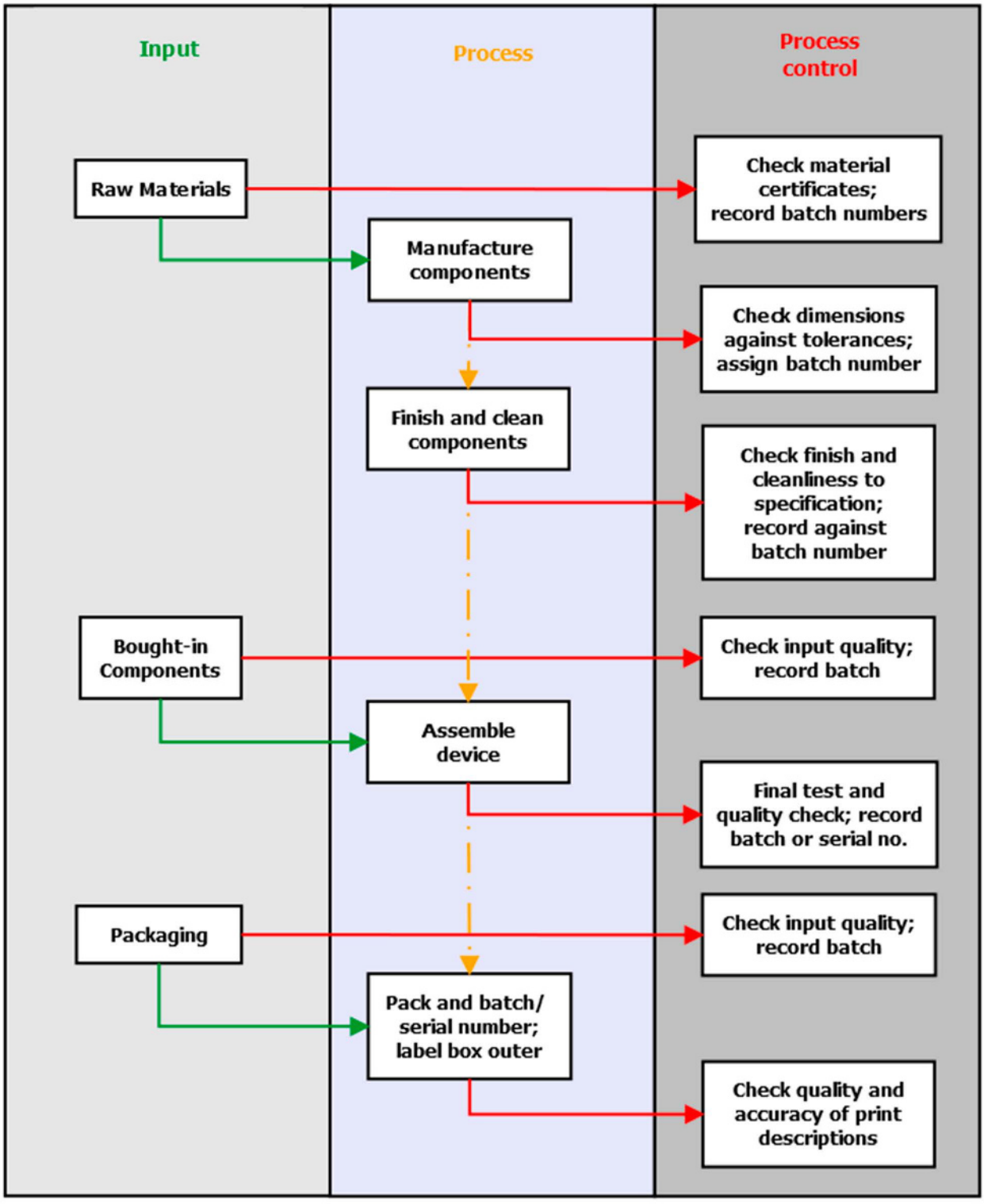
NOTE 2 *Attention is drawn to the potential requirements of the TPD [11], which is currently scheduled for Judicial Review at the European Court of Justice.*

5.3 Process control

Producers should ensure they have process controls and product specifications as outlined in **4.3**. This should include quality assurance of incoming materials and performance specifications for the final hardware.

NOTE *Figure 3 gives an example process for the production of a batch of e-cigarette hardware.*

Figure 3 – Example process for the production of a batch of e-cigarette hardware



5.4 General product risk assessment

Producers should undertake a risk assessment for each of their products, taking into account the normal and reasonably foreseeable uses of the products throughout their lifetime(s).

NOTE 1 *Attention is drawn to the GPSD [1] and EU guidance on HACCP [2].*

If a risk is identified, and is not covered by existing labelling requirements, existing electrical and other product safety legislation and/or recommendations in this PAS, steps should be undertaken to minimize the occurrence of the risk at the product design level insofar as this may be practical.

Any remaining risks should be communicated to consumers as a warning, either as part of the labelling, packaging or accompanying product instructions.

NOTE 2 *An example of a risk is the potential choking hazard associated with some small cartomizers.*

5.5 Toxicological risk assessment (TRA) of emissions

An analysis of emissions should be carried out for every specific model of atomizer or hardware product which includes an atomizer. Where an atomizer is being tested with a specific nicotine-containing e-liquid, the nicotine delivery to vapour should be measured, and expressed as mass per puff (see **4.9.5** and Annex B). The emissions should then inform a TRA carried out by a competent toxicologist. The TRA may be applied to a range of products where the analytes identified in their emissions fall within the range detailed in the TRA. The TRA should be repeated or updated if the analysis of emissions of the new product identifies an increase in analytes of interest.

Where hardware products are made from identical materials, and use identical atomizers, then a single TRA may be considered appropriate for this product family. Such a read-across should be supported by the toxicological data supplied.

NOTE 1 *An example where read-across would be supported is a family of different sized tanks composed of the same materials with a common atomizer.*

Hardware sold pre-filled with e-liquid should be assessed under the TRA as sold, i.e. with the pre-filled e-liquid in the device. However, devices which are sold empty, or for refilling with any available e-liquid, should be assessed under the TRA with a test solution. If the product instructions make any recommendations on compatible e-liquid composition(s), then testing should use the e-liquid(s) mentioned. Otherwise, the following test e-liquid should be used. Deviations should be justified on the basis of device compatibility or documented consumer use conditions.

The test solution should be prepared from 10 ml (±0.1 ml) each of Ph. Eur. nicotine and Ph. Eur. purified water, 90 ml (±0.5 ml) of Ph. Eur. glycerol and 390 ml (±0.5 ml) of Ph. Eur. propylene glycol (to create a solution of 78% v/v propylene glycol (PG), 18% v/v glycerol, 2% v/v purified water, and 2% v/v nicotine). All the ingredients for the test solution should be of pharmaceutical grade. The material composition of the device should inform the TRA.

NOTE 2 *The test solution is recommended because it is important that the emissions from the device itself can be assessed, rather than from a proprietary, formulated e-liquid. Furthermore, the results from different devices can be more usefully compared if each has been tested with a standard solution.*

Where an analyte of interest as described in **5.6** is identified in the emissions from the product, at a level of toxicological concern (see **5.5**), the source of these levels should be identified. Attempts should be made to alter the structure, components or design to reduce the levels present to a level that is toxicologically supportable. This should be verified by further TRA of emissions from the modified product. However, in identifying a supportable level, comparators may be used, such as workplace exposure levels, etc.

5.6 List of analytes of interest for emissions from hardware

Substances which should be monitored for emission by the hardware during VP use are listed in Table 4.

Table 3 – List of analytes of interest for emissions from hardware

Acetaldehyde 75-07-0 Acrolein 107-02-8 Formaldehyde 50-00-0	These should be measured with a view to minimizing the emissions so that they are toxicologically supportable.
Attention is drawn to the following analytes: Metals, to include: Aluminium 7429-90-5 Chromium 7440-47-3 Iron 7439-89-6 Nickel 7440-02-0 Tin 7440-31-5	The material composition of the hardware should be identified. Testing emissions generated by the hardware should be undertaken. ***NOTE** This testing will be informed by the composition of the hardware.* Some of the metals listed here are likely to be present in the emissions from hardware, so should be quantified and toxicologically evaluated to ensure that they are not present at levels of toxicological concern, as determined by a competent toxicologist.
Silica particles	If the wick is silica-based, the aerosol should be examined to ensure that needles or other dangerous small particles are not being generated. If needles or other dangerous small particles are identified in the aerosol, the wicking material grade should be changed.

5.7 Substantial modification

5.7.1 General

If a producer modifies a hardware product so that it produces different emissions from the original, e.g. delivers more nicotine, has higher carbonyl emissions, etc., then a new technical dossier should be produced by the producer for the modified product.

***NOTE 1** Examples of substantial modification include:*

a) changes in the voltage/wattage to the atomizer, or resistance of the heating element;

b) a change of any of the device materials that are in contact with the liquid or aerosol;

c) a change of specification of a component which has the potential to affect the CRP.

Minor modifications which assessment by the manufacturer indicates do not affect CRP should be noted in the technical dossier but do not require a new technical dossier.

***NOTE 2** An example of a modification that does not affect CRP would be making a device available in different colours (subject to risk assessment of the proposed paint).*

5.7.2 Imported products

Importers should request the technical dossier and TRAs from the manufacturers.

***NOTE** Where products are manufactured outside the EU and imported for sale within that market, importers take on the legal obligations as if they were the manufacturer. Attention is drawn to CE [2] [3] and RoHS [4] documentation requirements, as well as WEEE and batteries regulations [7] [8]. Attention is also drawn to the ECITA Industry Standard of Excellence (ISE) [19], which sets out the legal obligations on manufacturers.*

Importers should also create their own technical dossiers (see **5.2**).

5.7.3 Batteries and chargers

Importers of batteries and chargers should ensure that they request the certificates and full test reports relating to legal compliance testing from their suppliers.

Batteries should be designed to meet the requirements of BS EN 62133.

***NOTE** Attention is drawn to CE [2] [3] and RoHS [4] legislation, and batteries regulations, including the requirement for a material safety data sheet (MSDS) for batteries in transit, as well as BS EN 60335, Safety of household electrical appliances, and BS EN 60950, Information technology equipment – Safety.*

5.8 Exemptions

Producers who supply batteries for use in VP with and/or without chargers to consumers should have documentary evidence to demonstrate that these products have been tested to ensure they can function safely during use. VP which do not create emissions, i.e. batteries, chargers, drip tips, cases, etc., do not require emissions testing.

Producers of atomizers should undertake emissions testing for the atomizer, with the test e-liquid in **5.5**, unless sold pre-filled with e-liquid, in which case, the product's emissions should be tested using the product as a composite whole.

NOTE 1 *Attention is drawn to CE [2] [3] and RoHS [4].*

NOTE 2 *See Annex B for the test parameters for emission solutions.*

Mods, with and/or without atomizers, need not be produced in manufacturing facilities to the standard required for e-liquids, but prior to shipping/packaging, devices should be thoroughly cleaned to ensure that microbial and other contamination is minimized.

6 Vaping product labelling, packaging and instructions

6.1 General

All text on product labelling, packaging and instructions should be presented in font and layout that facilitates readability, and be presented to consumers using language that can be easily understood, without being ambiguous.

6.2 Labelling

6.2.1 General

Any labelling directly on products, as well as outer packaging of all e-liquid containing products, based on PG and/or glycerol, with a nicotine concentration up to 2.5% (25 mg/ml), as well as e-liquids without nicotine, should carry the text: "CAUTION: Keep out of the reach of children and pets; Only for use in electronic cigarettes; Seek medical advice if you feel unwell", followed by the additional text "Refer to device manufacturer's instructions for refilling."

NOTE 1 *Attention is also drawn to labelling requirements in the RoHS [4] and WEEE [7] Directives, as well as the CLP [5] for VP based on PG and/or glycerol, with a nicotine concentration above 2.5% (25 mg/ml). For nicotine containing solutions of between 2.5% (25 mg/ml and 5% (50 mg/ml), at the time of publication the CLP [5] classification category is category 4 for both oral and dermal exposures.*

NOTE 2 *Attention is also drawn to the label requirements in the TPD [11].*

VP should also carry a clearly visible and legible sign specifying that these products are only for purchase by those over 18.

NOTE 3 *Attention is drawn to the trademark ownership of the number 18 in a circle by the British Board of Film Classification (BBFC).*

The nicotine content should be clearly indicated, in % w/v and or mg/ml for refill containers with pre-filled products either marked in the same way, or with total nicotine content in mg. Testing documentation should support that it is stated accurately.

Many flavourings are supplied in solution using PG as a solvent, so if producers are producing e-liquids to be marketed as "PG-free", care should be taken to ensure they are fully free of PG by referring to the supporting documentation supplied with the ingredients. If in any doubt, producers should discuss the ingredients in the products directly with their suppliers.

NOTE 4 *Propylene glycol is toxic to felines.*

All VP supplied with e-liquid (either pre-filled or separately) should display an expiry date, batch number and list of ingredients in weight order.

All e-liquids should remain within specification (according to the technical dossier) throughout the indicated shelf life to ensure that the labelling remains accurate and is not misleading to consumers.

6.2.2 Allergy warnings

Some e-liquid flavourings may contain food allergens. If a risk assessment identifies such a risk, the finished product should bear the following warning on the label: "May contain traces of [allergen]".

NOTE *Attention is drawn to the FSA guidelines on food allergy labelling https://www.food.gov.uk/business-industry/guidancenotes/labelregsguidance.*

Some e-liquid ingredients (especially flavourings) are known to have the potential to cause skin sensitization, also known as contact sensitization-type allergic reactions. These can elicit allergic responses in people who are sensitive to those compounds at levels that cause no problem for the wider general public. To ensure consumers are adequately informed, the presence of these ingredients should be mentioned on the label, and/or supplied with the product information leaflet if they are present in the e-liquid at levels identified as a concern by a TRA.

Respiratory sensitizers should not be present in e-liquid (see Table 2).

6.2.3 Responsible handling instructions

Producers should provide consumer care contact details for feedback on products, including complaints and adverse events.

The device operating instructions should include safety information for charging, safe storage and handling, cleaning and maintenance, and instructions on proper operation to facilitate effective and safe use by consumers.

If the device is or includes an atomizer, the instructions should inform the consumer about the levels at which the atomizer has been tested and is suggested for use. It should also include information on safe refilling of the device, if appropriate.

NOTE *Some devices are able to operate at higher input power levels than are desirable or even safe for end users, in the same way that many cars are capable of being driven at 130 mph, but this is not how they should be driven under normal conditions.*

These instructions can appear either on the outside packaging or in an insert in the packaging at the producer's discretion.

6.3 Packaging

6.3.1 General

For VP where e-liquid is supplied, the outer packaging should carry a clearly legible statement of the nicotine concentration of the e-liquid even if it is 0% in either % w/v or mg/ml.

For pre-filled e-cigarettes and their refill cartridges, the outer packaging could instead indicate the total nicotine content of each unit of the product.

6.3.2 Child-resistant packaging

Packaging for e-liquids sold separately from devices should conform to BS EN ISO 8317.

Packaging for pre-filled e-cigs should conform to BS EN 862.

All VP supplied with e-liquid, with and/or without nicotine, should have documentary evidence to support that they are child-resistant at the point of supply. If VP devices are not inherently child-resistant, they should be supplied in child-resistant packaging, with documentary evidence in support.

6.3.3 Tamper evident packaging

There should be a visible tamper-evident seal on the packaging of pre-filled e-cigs, e-liquid atomizing devices sold separately, e-liquids in bottles, and all other VP where tampering may be of concern.

The tamper-evident package should have one or more indicators or barriers to entry which, if breached or missing, can be reasonably expected to provide visible evidence to consumers that tampering has occurred.

Where VP are supplied in boxes, tamper-evident mechanisms should be used at all possible points of entry to the product, so that they cannot be by-passed.

The tamper-evident feature should be designed to remain intact and should remain intact when handled in a reasonable manner during manufacture, distribution and retail display.

NOTE *Although it seems of little practical use to supply batteries in tamper-evident packaging, however, it is extremely important for any type of atomizing device where the user will be exposed to any contamination.*

6.4 Bottle design for refilling safety

Bottles should be fitted with a delivery spout capable of accurately delivering refill liquid into the appropriate part of the atomizer/tank without spillage.

6.5 Additional instructions and information

Unit packets of electronic cigarettes and refill containers should include a leaflet giving information on use and storage (as given in **6.2.3**).

This leaflet should also state that the products are unsuitable for those under 18, or who are not already smoking or vaping. VP with nicotine should also give contra-indications and warnings for specific risk groups. The exact nature of these is likely to depend on the exact product in question, but some recommendations are included in the following list:

a) The leaflet should include information on possible adverse effects, toxicity, and provide contact details for the organization within the EU responsible for production or importation.
b) The product should be contraindicated for people who are hypersensitive to nicotine, or any of the other ingredients.
c) Nicotine is known to cross the placental barrier, and so has risks for the foetus, however these risks are considered to be lower than for continuing to smoke. A suitable warning may therefore be "Consult a healthcare professional before using during pregnancy".
d) Similar warnings should also be given to people with CVD, renal or hepatic impairment, adrenal or thyroid gland disorders, diabetes or lung disorders.
e) The risk to small children, e.g. choking hazard risk for small parts such as cartomizers, should also be emphasized.

f) The instructions for use should contain information on what is a suitable charger for the product.

g) VP should be provided with clear instructions to the user not to use the device in high oxygen environments.

NOTE 1 *Attention is drawn to the British Compressed Gases Association leaflet* L16 The safe use of electronic cigarettes and other electronic devices used near medical oxygen *[28].*

NOTE 2 *Attention is drawn to the requirements of the TPD [11], which at the time of publishing this PAS, is under review by the European Court of Justice.*

7 Vaping product claims

7.1 Marketing claims

7.1.1 General

All product marketing and performance claims should be supported by documentary evidence demonstrating that the claim is accurate and not misleading.

7.1.2 Health claims

Claims made in order to market VP, whether directly on labelling and/or packaging, and/or on websites and/or on other marketing materials, should be free of medicinal claims, and should be accurate and not misleading.

For the avoidance of doubt, there should be no claims made for the product relating to quitting smoking, satisfying cravings, etc., as these are deemed to be medicinal claims.

NOTE *Attention is drawn to the Medicinal Products Directive 2001/83 [10] and to the Advertising Standards Authority Committees on Advertising Practice's Guidance [18].*

7.1.3 Marketing to children, youth and non-smokers

Marketing claims and campaigns should not be deliberately targeted at children, youth or non-nicotine users.

NOTE *Attention is drawn to the Advertising Standards Authority Committees on Advertising Practice's Guidance [18].*

7.2 Performance claims

7.3 General

Smoking and vaping are very different habits, so performance claims should be carefully constructed so as to avoid confusion and disappointment for the consumer.

All performance claims made should remain accurate over the expected lifetime of the product and its components.

7.3.1 Puffs

The number of puffs on an electronic cigarette may be expressed as a total puff count. Any direct comparisons made with tobacco cigarettes should be qualified by making it clear that such comparisons are obtained using a standard smoking machine, using a standardized regime, e.g. 55/3/30 (a 55 ml puff of a 3 s duration with 30 s between start of puffs), and this might not be the same as human smoking or vaping.

First generation "cigalike" products resemble a cigarette and so consumers can be all too easily misled into thinking that the switching from smoking cigarettes to using VPs is straightforward. This is not the case, so it is important to ensure that consumers are not disappointed by the products, potentially misleading them to believe that they do not offer a suitable alternative to smoking tobacco. The information provided to consumers should therefore be so constructed as to allow them to make an informed decision about what they can expect in terms of the product's performance.

NOTE *Refillable devices do not resemble a cigarette, and yet smokers switching to such devices may need some guidance in learning how to switch from smoking cigarettes to using VPs.*

Information supplied with any VP device should stress that consumer experience of using a VP depends on device characteristics, nicotine concentration, total nicotine, puff duration, puff intensity and puff frequency.

7.3.2 Battery and atomizer life

Battery and atomizer life varies according to the quality of the product. Different batteries might have different recharging cycles; different atomizers will last for varying periods of use. Therefore, if performance claims are to be made about battery and/or atomizer longevity, these should also be supported by documentary evidence, such as battery/atomizer performance test reports which relate directly to the product for which the claims are made, and which clearly demonstrate that the product reliably achieves the performance claimed.

Rechargeable batteries are already required to be marked with capacity in mAh, but it might also be useful to provide this information on non-rechargeable batteries to provide consumers with an easily comparable measure of battery size.

NOTE *Attention is drawn to the Batteries and Accumulators (Placing on the Market) Regulations 2008 [29] and the Waste Batteries and Accumulators Regulations 2009 [30].*

For both batteries and atomizers, information supplied with the product should indicate the likely life-time of the product, with reference to actual test conditions the device has undergone.

Annex A (informative)
Worked example of batch traceability

A.1 General

If a supplier contacts a producer to inform them of a problem with a specific batch of materials they have supplied, the producer needs to be able to identify which (if any) of his raw materials, flavourings and/or final products are affected. The documentation and process control described in Clause **4** can make this a relatively simple process, as per this worked example.

A.2 Worked example

A flavouring supplier (FS) contacts an e-liquid producer (ELP) to inform them that a problem has been identified with certain batches of their flavourings. The ELP needs the following information, which the FS provides:

a) the name of the flavour product(s) affected;

b) the individual batch number(s) affected.

For this example, the problem has been identified with an apple flavour from batch numbers RRR310516 and HHH180716 and vanilla flavouring from batch numbers ZZZ300416, PPP180216 and JJJ250516.

The FS assures the ELP that these are the only batches affected, and that other batches of these flavourings are not a cause for concern.

The ELP's batch record system allows the ELP to identify which specific products in their range need corrective action. First of all, the ELP can refer to their batch records for recipes which use apple and/or vanilla flavouring.

In the sample batch records in Table A.1 to Table A.4., the affected batches identified by the FS are emphasized in coloured boxes (see Tables A.1 and A.3), so it is clear that the products affected would be the fruit mix e-liquid 1.8% PG/AG with UBR FPE29765/V and the apple e-liquid 1.1% PG/Glycerol with UBR APE97211/P, i.e. only those affected by the particular batches recalled by the FS.

NOTE *Where percentage concentrations are given throughout these worked examples in Annex A, included Table A.1 to Table A.4 and Figure A.1, this refers to nicotine percentage weight by volume (% w/v).*

Batches identified as needing to be withdrawn by the FS in the batch record sheets in Tables A.1 to Table A.4 are indicated in coloured boxes, and the finished products which require withdrawal are outlined in red in the traceability model at Figure A.1.

Other batches of these products, made with different batches of flavourings which were not affected, would not need to be recalled or withdrawn from sale.

None of the products containing vanilla flavouring would need to be recalled or withdrawn in this example because the batch numbers do not match those identified by the FS as problematic.

Table A.1 – Example fruit mix batch record sheet

Batch record						
Product name: Fruit mix e-liquid 1.8% PG/AG				UBR: FPE29765/V		
Facility check				**By operator**	**Checked by**	**Date**
Cleanliness of facility				***JW***	***STP***	***01/05/15***
Cleanliness of equipment				***JW***	***STP***	***01/05/15***
Component process	**Component UBR**	**Quantity required**	**Quantity added**	**By operator**	**Checked by**	**Date**
Add PG/AG only base e-liquid (5.4%)	PA541N	33.334 kg	***33.334 kg***	***JW***	***STP***	***01/05/15***
Add AG	AG9678A	28.333 kg	***28.333 kg***	***JW***	***STP***	***01/05/15***
Add PG	0109/A	28.333 kg	***28.333 kg***	***JW***	***STP***	***01/05/15***
Add apple flavouring	RRR310516	3.333 kg	***3.333 kg***	***JW***	***STP***	***01/05/15***
Add strawberry flavouring	QQQ432196	3.333 kg	***3.333 kg***	***JW***	***STP***	***01/05/15***
Add cherry flavouring	CCC237961	3.334 kg	***3.334 kg***	***JW***	***STP***	***01/05/15***
Mix product	N/A	5 mins	***5 mins***	***JW***	***STP***	***01/05/15***
Batch approved by						
Name: KVD		Sign: ***KVD***		Date: ***01/05/15***		

Table A.2 – Example strawberry batch record sheet

Batch record						
Product name: Strawberry e-liquid 2.4% AG			UBR: SSE45876/R			
Facility check				**By operator**	**Checked by**	**Date**
Cleanliness of facility				***JW***	***STP***	***01/05/15***
Cleanliness of equipment				***JW***	***STP***	***01/05/15***
Component process	**Component UBR**	**Quantity required**	**Quantity added**	**By operator**	**Checked by**	**Date**
Add AG-only base e-liquid (5.4%)	AG549N	44.445 kg	***44.445 kg***	***JW***	***STP***	***29/05/15***
Add aqueous glycerol	G879V	45.555 kg	***45.555 kg***	***JW***	***STP***	***29/05/15***
Add strawberry flavouring	QQQ432196	8.850 kg	***8.850 kg***	***JW***	***STP***	***29/05/15***
Add vanilla flavouring	ZZZ300417	1.150 kg	***1.150 kg***	***JW***	***STP***	***29/05/15***
Batch approved by						
Name: KVD		Sign: ***KVD***		Date: ***29/02/15***		

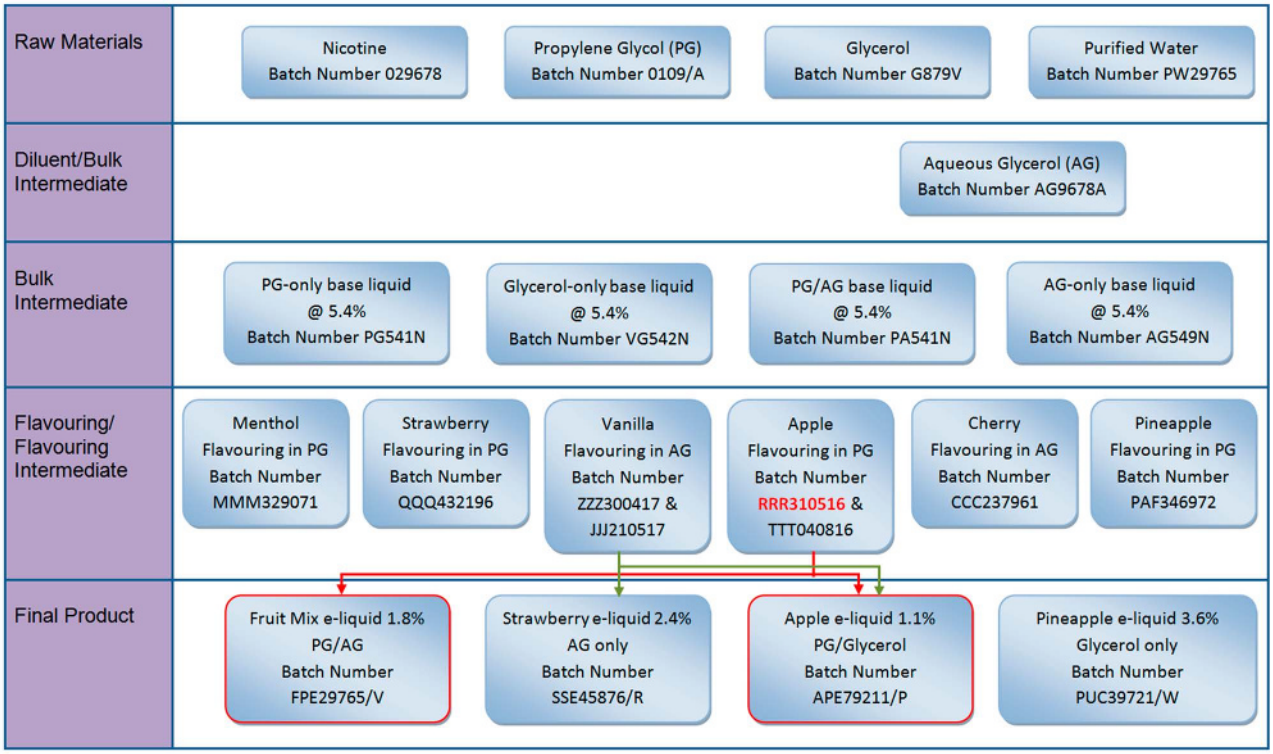
Table A.3 – Example apple batch record sheet

Batch record						
Product name: Apple e-liquid 1.8% PG/AG				UBR: AE37549/W		
Facility check				**By operator**	**Checked by**	**Date**
Cleanliness of facility				***JW***	***STP***	***29/04/15***
Cleanliness of equipment				***JW***	***STP***	***29/04/15***
Component process	**Component UBR**	**Quantity required**	**Quantity added**	**By operator**	**Checked by**	**Date**
Add glycerol only base e-liquid (5.4%)	VG542N	20.370 kg	***20.37 kg***	***JW***	***STP***	***29/04/15***
Add propylene glycol	0109/A	34.815 kg	***34.815 kg***	***JW***	***STP***	***29/04/15***
Add glycerol	G879V	34.815 kg	***34.815 kg***	***JW***	***STP***	***29/04/15***
Add apple flavouring	RRR310516	3.500 kg	***3.500 kg***	***JW***	***STP***	***29/04/15***
	TTT040816	3.500 kg	***3.500 kg***			
Add vanilla flavouring	HHH180717	3.000 kg	***3.000 kg***	***JW***	***STP***	***29/04/15***
	JJJ 210517	1.000 kg	***1.000 kg***			
Mix product	N/A	5 mins	***5 mins***	***JW***	***STP***	***29/04/15***
Batch approved by						
Name: KVD		Sign: ***KVD***		Date: ***01/05/15***		

Table A.4 – Example pineapple batch record sheet

Batch Record						
Product name: Pineapple e-liquid 3.6% Glycerol				UBR: PUC39721/W		
Facility check				**By operator**	**Checked by**	**Date**
Cleanliness of facility				***JW***	***STP***	***29/05/15***
Cleanliness of equipment				***JW***	***STP***	***29/05/15***
Component process	**Component UBR**	**Quantity required**	**Quantity added**	**By operator**	**Checked by**	**Date**
Add glycerol only base e-liquid (5.4%)	VG542N	66.667 kg	***66.667 kg***	***JW***	***STP***	***29/02/15***
Add glycerol	G879V	23.333 kg	***23.333 kg***	***JW***	***STP***	***29/02/15***
Add pineapple flavouring	PAF346972	6.600 kg	***6.600 kg***	***JW***	***STP***	***29/02/15***
Add apple flavouring	TTT040816	0.600 kg	***0.600 kgs***	***JW***	***STP***	***29/02/15***
Add cherry flavouring	CCC237961	2.800 kg	***2.800 kg***	***JW***	***STP***	***29/02/15***
Mix product	N/A	5 mins	***5 mins***	***JW***	***STP***	***29/05/15***
Batch approved by						
Name: KVD		Sign: ***KVD***		Date: ***29/05/15***		

Figure A.1 – Batch traceability model for this worked example



Annex B (informative)
Metals and compounds to be monitored in e-liquids and the emissions (or condensates of the emissions) of vaping products

B.1 General

Tests are conducted on e-liquids to ensure that impurities, contaminants and unwanted components are not present at levels of toxicological concern, as identified by a competent toxicologistand to demonstrate that nicotine content is accurately described on the packaging and labelling (see **4.6.9**).

Tests are also conducted on the emissions from both e-liquid (see **4.9.5**)and hardware (see **5.5**) to ensure that chemical changes during the vapourization process are not creating compounds which would be unsafe for inhalation by the consumer. Analytical techniques used are capable of detecting the analytes given in Table B.1 and Table B.2 to a level which is able to inform the TRA.

The precise analytical technique for testing is not given as any technique (or combination of techniques) is considered suitable providing it is capable of detecting the materials listed in Table B.1 and Table B.2 to appropriate detection limits, e.g. gas chromatography/ mass spectrometry for identifying and quantifying organic chemical species (with reference to internal or external standards), with atomic emissions spectroscopy/inductively coupled plasma for identifying and quantifying metals.

For the purpose of this annex, "liquid(s)" is the term used for e-liquids and emissions solutions, and which can be submitted as samples for testing and analysis.

B.2 Metals

The liquid sample for testing shall be analysed for the content of metals as shown in Table B.1.

Table B.1 – Metals to be analysed

Metal	CAS Number
Aluminium	7429-90-5
Chromium	7440-47-3
Iron	7439-89-6
Nickel	7440-02-0
Tin	7440-31-5

The device materials dictate which metals are analysed and whether any additional metals are to be considered.

B.3 Compounds

The e-liquid sample for testing shall be analysed for the compounds shown in Table B.2.

Table B.2 – Compounds to be analysed

Compound	CAS Number
Acetaldehyde	75-07-0
Acrolein	107-02-8
Formaldehyde	50-00-0
Nicotine	54-11-5

It might be necessary to test for other compounds in addition to this list, based on the thermal degradation profile of the ingredients. Toxicological and other scientific advice should be sought when changing the formulation of the product to identify these potential compounds.

Nicotine delivery to vapour is measured, and expressed as mass per puff. This can be either measured directly or extrapolated between measured points, if linearity can be demonstrated.

NOTE *Attention is drawn to the TPD [11], which might result in a further requirement for other specific emissions to be measured.*

The quantities of other components can be approximated using a semi-quantitative technique (for example by using peak area measurements in gas chromatography or high performance liquid chromatography).

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Food Standards Agency (FSA) labelling guidance *https://www.food.gov.uk/business-industry/guidancenotes/labelregsguidance*

British Standards Institution (BSI)

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