Going International: Are Your Vape Products EU Compliant?

31 July 2017

The Webinar Will Begin Shortly

DIAL-IN FOR AUDIO:
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Code: 434 4318
Going International: Are Your Vape Products EU Compliant?

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Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual’s specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depend on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are ours alone and not those of the our clients.
Azim joined Keller and Heckman in 2010 and practices in the area of FDA law with a focus on food, tobacco and e-vapor products.

Azim advises e-vapor manufacturers, distributors, retailers and trade associations on matters of state, FDA and international regulatory compliance.

Co-authored Food and Drug Law Institute’s Tobacco and Nicotine Delivery Regulation and Compliance manual

Follow Azim on Twitter @ECIGattorney
Marcus is a partner at Keller and Heckman in Brussels, Belgium.

Marcus’s practice is focused on ensuring products gain access to the EU Single Market, comply with EU law, and product defence.

His clients are generally active in the chemicals, tobacco, e-cigarette, and consumer product industries.

Marcus has advised and litigated for clients in the tobacco, e-cigarette, e-liquid and vaping industries and the upstream supplier chemical industries.

Marcus has authored the FDLI “Tobacco Regulation and Compliance” chapter on “Selected Topics in the Regulation of Tobacco Products in the European Union”.

Marcus is a solicitor with the Law Society of Ireland, and the Law Society of England and Wales.
Overview

- Update on FDA Compliance Deadlines
- EU Background
  - EU legal framework
  - New TPD
- Other EU requirements
  - General consumer product: GPSD, Directive on liability for defective products; NB standards, CEN/TC 437, RAPEX, etc
  - Chemical: REACH, CLP, etc
  - Other: Energy Labeling Directive and Eco-Labeling Regulation;
- Other issues:
  - CE marking, Standards, national requirements, national standards, collective redress systems, etc
  - International requirements and standards? BREXIT?
## Compliance Deadlines Rapidly Approaching

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Deadline for Large-Scale Manufacturers</th>
<th>Deadline for Small-Scale Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration of U.S. manufacturing establishments and submission of List of Products manufactured in such establishments</td>
<td>September 30, 2017</td>
<td></td>
</tr>
<tr>
<td>Submission of Health Document Notification</td>
<td>February 8, 2017</td>
<td>November 8, 2017</td>
</tr>
<tr>
<td>Submission of Ingredients Listing Reports</td>
<td>November 8, 2017</td>
<td>May 8, 2018</td>
</tr>
<tr>
<td>Premarket Tobacco Product Application (PMTA) or Substantial Equivalence (SE) Reports for products on market as of August 8, 2016</td>
<td>August 8, 2021 for Combustible Products (cigars, hookah)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>August 8, 2022 for Non-Combustibles (vapor)</td>
</tr>
<tr>
<td>Submission of Harmful and Potentially Harmful Constituents (HPHCs) Reports</td>
<td></td>
<td>November 8, 2019</td>
</tr>
</tbody>
</table>
European Union Compliance
Acronyms

- Old/Current TPD - Directive 2001/37/EU
- Legal challenge: C-477/14
- CLP – Regulation 1272/2008
- ECHA – European Chemical Agency
- MSCA – Member State Competent Authority
- MS – Member State
- EU – European Union
- CARACAL – Competent Authorities for REACH and CLP
- COM – European Commission
Background
DIRECTIVES

DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 3 April 2014
on the approximation of the laws, regulations and administrative provisions of the Member States
concerning the manufacture, presentation and sale of tobacco and related products and repealing
Directive 2001/37/EC
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 53(1), 62 and 114
thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (1),

Acting in accordance with the ordinary legislative procedure (1),

Whereas:
Core Requirements Under New TPD

TPD apply?
1. Product safety and quality requirements
2. Notification requirements
3. Annual reporting requirements
4. Packaging and labelling requirements (including leaflet)
5. Advertising restrictions and prohibitions
6. Cross border distance selling requirements
7. Other requirements (Corrective action and product recalls)
Other Issues – MS Discretion/Single Market

MSs have discretion to adopt measures relating to (non exhaustive list):

- **Scope:** Zero nicotine e-liquids
- **Product requirements:** Rules on flavours (paragraph 47, Preamble)
- **Notification:** Fees charged for notification and notification requirements
- **Packaging and labelling:** Language and health warnings Art 20(4)(b)(iii)
- **Advertising:** Restrictions on poster advertising etc
- **Cross border distance selling**
- **Transitional provisions/phase out deadlines**
- **Vape free zones/environment** [NB Future EU action? Council Recommendation on Smoke Free Environment 2009]
- **Use/sale:** Age limit for electronic cigarettes or refill containers use/sale
- **NB Waste / circular economy**
- **Standards** (NB France, UK, etc.)

NB BREXIT?
National Law Requirements (e.g. Germany)

Prohibited additives in tobacco products

1. Vitamins and the following other additives that create the impression that a tobacco product would offer a health benefit or would carry lower health risks:
   a) Amino acids and modified amino acids which are approved for dietary foods pursuant to § 7(1) sentence 1 point 1, in conjunction with Appendix 2 category 3, of the Order on dietetic foodstuffs, as amended, along with S-Adenosyl methionine and L-6-Hydroxytryptophan
   b) Carnitine
      L-carnitine
      L-carnitine hydrochloride
      L-carnitine L-tartrate
   c) Flavonoids and phospholipids with an antioxidative effect
   d) Sodium selenite

2. Caffeine, taurine or the following other additives and stimulant compounds that are associated with energy and vitality:
   a) Maltodextrin
   b) Components, including processed components, extracts and oils, of the coffee plant and coffee beans
   c) Components, including processed components, extracts and oils, of the tea bush Camellia sinensis L. Kuntze
   d) Components, including processed components, extracts and oils, of the guarana plant
   e) Components, including processed components, extracts and oils, of the yerba mate
   f) Thujone

3. Additives having colouring properties for emissions

4. The following additives in the case of tobacco products for smoking that facilitate inhalation or nicotine uptake:
   a) p-menthane-3 substituted and modified compounds, including
      p-menthane-3-carboxamide, including p-menthane-3-N-[alkyl]carboxamide
      p-menthane-3-ester
      p-menthane-3-ether
      p-menthane-3-carboxylic acids and their esters
   b) p-menthene alcohols and their esters
   c) The following compounds:
      3,4-dihydro-3-(2-hydroxyphenyl)-6-(3-nitrophenyl)-(1H)-pyrimidine-2-oxo (CAS No 36945-98-9)
      2-isopropyl-N,2,3-trimethylbutyramide (CAS No 51115-67-4)
      Isopulegol (CAS No 7786-67-6 or 89-78-2)
      1-(di-sec-butyl-phoshine)-heptane
   d) The following substances:
      aa) Menthol (CAS No 1490-04-6)
      (-)-menthol (CAS No 2216-51-5)
      (+)-menthol (CAS No 15356-60-2)
      bb) Menthone (CAS No 89-80-5)
      (-)-menthone (CAS No 14073-97-3)
      (+)-menthone (CAS No 3391-87-5)
      L-carvone (CAS No 6485-40-1)
      Geraniol (CAS No 106-24-1)
      Linalool (CAS No 78-70-6)
      1,8-cineole (Eucalyptol) (CAS No 470-82-6)
      Hydroxycitronellal (CAS No 107-75-5)
   e) The following substances derived from plants:
      Oils and components which originate from plants of the genera Mentha, Eucalyptos, Ocimum, Thymus and Salvia

5. The following additives that have CMR properties in unburnt form:
   a) Substances which are classified as category 1A, 1B or 2 CMR substances in
COMMISSION IMPLEMENTING DECISION (EU) 2015/2183

of 24 November 2015

establishing a common format for the notification of electronic cigarettes and refill containers

(notified under document C(2015) 8087)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (1), and in particular Article 20(13) thereof,

Whereas:

(1) Directive 2014/40/EU provides that manufacturers and importers of electronic cigarettes and refill containers are to submit to the competent authorities of the Member States concerned a notification of any such products which they intend to place on the market or which are already placed on the market on 20 May 2016. The information should be submitted 6 months before the intended placing on the market of new or substantially modified products. The format for that notification should be laid down.

(2) The experience gained and the knowledge acquired with existing formats for the reporting of tobacco ingredients, where relevant, should be taken into account when developing the format.

(3) A common electronic notification format for submission of information on electronic cigarettes and refill containers should allow Member States and the Commission to process, compare, analyse and draw conclusions from the information received. The data will also provide a basis for assessing health impacts associated with these products.

(4) A common electronic entry gate for submission of data is essential to ensure uniform application of the notification obligations set out in Directive 2014/40/EU. In particular, a common entry gate facilitates and harmonises the submission of data from the manufacturer or importer to the Member States. Streamlining the submission process also reduces administrative burden for manufacturers, importers and national regulators and facilitates comparison of data. To facilitate multiple uploads, a repository might be established at the level of the common entry gate to allow for references to non-confidential documents.
Daily new products

Source of information: EU Commission (SANTE)
Total number of products

Source of information: EU Commission (SANTE)
# State of play EUCEG project

Submissions in production - figures

<table>
<thead>
<tr>
<th>Period</th>
<th>08 September</th>
<th>28 of October</th>
<th>15 of December</th>
<th>March 2017</th>
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<td>Nº of industries submitting in production</td>
<td>41</td>
<td>127</td>
<td>522</td>
<td>787</td>
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<tr>
<td>Tobacco products</td>
<td>378</td>
<td>2436</td>
<td>21612</td>
<td>23246</td>
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<tr>
<td>E-cigarette products</td>
<td>1562</td>
<td>3888</td>
<td>73613</td>
<td>96541</td>
</tr>
<tr>
<td>Total number of products</td>
<td>1940</td>
<td>6324</td>
<td>95225</td>
<td>119787</td>
</tr>
<tr>
<td>Total number of submissions treated by the system</td>
<td>6653</td>
<td>29808</td>
<td>308198</td>
<td>499497</td>
</tr>
</tbody>
</table>

Source of information: EU Commission (SANTE)
More than 27,569 notifications
MHRA – requests for further information?
Initially verifying invoicing and confidentiality issues

MHRA is seeking information on the likely number of e-cigarette notifications we will receive over the next four years. MHRA aims to ensure the UK fees for e-cigarette notifications are set at a fair and consistent level, and we need information on future notification volumes to do this.

We are asking about the next four years as we aim to recover our costs of regulation over a five year period, and the notification system has been running for one year.

The following survey is aimed at all business who may submit a UK e-cigarette notification.

We would be grateful if you could answer the following questions where you are able. We understand that you may not be certain of the answers, but we would be grateful for any estimates you can provide. Better information on volumes will reduce the likelihood that MHRA will make large unexpected changes to fees, providing certainty for those in the e-cigarette industry.

Please note that this survey closes at 23:59 on Sunday 9 July.

1. How many e-cigarette notifications did your business make before 31 March 2017?

2. How many new e-cigarette notifications does your business expect to make in the following financial years (1 April - 31 March)?
Manufacturers and importers of electronic cigarettes and refill containers must submit to MSCAs:

(i) comprehensive **data on sales volumes**, by brand name and type of the product;

(ii) **information on the preferences of various consumer groups**, including young people, non-smokers and the **main types of current users**;

(iii) the **mode of sale** of the products; and

(iv) **executive summaries of any market surveys** carried out in respect of the above, including an English translation thereof.
Other EU law
(i.e. excluding New TPD)
General consumer product:

GPSD, Defective Products Directive, standards, RAPEX, etc.
DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure referred to in Article 251 of the Treaty (1), in the light of the joint text approved by the Conciliation Committee on 2 August 2001,

Whereas:

(1) Under Article 16 of Council Directive 92/59/EEC of 29 June 1992 on general product safety (1), the Council was to decide, four years after the date set for the implementation of the said Directive, on the basis of a report of the Commission on the experience acquired, together
New CEN/TC 437 'Electronic cigarettes and e-liquids'

In January 2015 CEN created new Technical Committee - CEN/TC 437 'Electronic cigarettes and e-liquids'. Our French member, AFNOR, holds the secretariat of this new body.

**Kick-off meeting**

The first meeting will take place in AFNOR, Paris on 22 June 2015. It is important for us that all categories of affected stakeholders are consulted and involved in the work, including, in particular, manufacturers, suppliers and end-users. Therefore, interested stakeholders are invited to contact their National Standardization Bodies.

**Aim of the Technical Committee**

The aim is to develop European Standards dealing with safety aspects for both e-cigarettes (mechanical, thermal, electrical and chemical hazards etc.) and e-liquid (the content of chemicals including nicotine and formaldehyde, black listed components: heavy metals, allergens etc.), as well as analytical methods providing a basis for determination and quantification of all chemical components stated in the requirements relating to safety of these products.

Currently there are no European standards defining safety requirements for electronic cigarettes and e-liquids, neither on related test methods. The proposed standardization activity will support the already identified need to create requirements and suitable measurement techniques for the fast growing market of e-cigarettes and ensure protection for end-users.

More information soon to come on our [Consumer products webpage](#).

[Source of information: Extract from CEN website]
2. Notification Requirements

 Notification requirement:
Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. Article 20(2) New TPD

 Notification must be made: “…six months before the intended placing on the market…“ Notification for products on market on the market on 20 May 2016: “…the notification shall be submitted within six months of that date…“ i.e. before 20 November 2016.

Non EU products placed on EU market? Made available to consumers located in the EU? Documentary proof? Product modifications?

 Notifications must be made “in electronic form”. On 24 November 2015 common format for the notification published in OJ.
BREAKING NEWS

Toddler who ingested liquid nicotine passes away

A two-year-old girl who ingested liquid nicotine from an electronic cigarette passed away on Tuesday evening in Hadassah Medical Center in Jerusalem's Ein Karem, Army Radio reported.

Police spokesman Micky Rosenfeld said the girl’s parents were questioned to determine whether the cigarette came from them or a different source.

**Alert number:** A12/0929/16  
**Product:** Liquid for electronic cigarettes  
**Name:** Milk and Chocolate  
**Batch number / Barcode:** Unknown  
**Risk level:** Serious  
**Risk type:** Chemical

The product contains nicotine yet the presence of nicotine is not adequately reported on the labelling. The bottle containing the mixture does not bear an adequate label, the user therefore has no information on the dangers incurred when the product comes into contact with the skin or if it is ingested. In addition, the product can be misleading for consumers as it refers to a drink both in respect of packaging and in terms of organoleptic characteristics, i.e. intense aroma of cocoa. The product does not comply with the Regulation on the classification, labelling and packaging of substances and mixtures (CLP) and the requirements of Directive 87/357/EEC on products which, appearing to be other than they are, endanger the health or safety of consumers.

**Measures ordered by public authorities:** Ban on the marketing of the product and any accompanying measures

**Description:** Liquid for e-cigarettes. External packaging: a container made of yellow plastic with an adhesive label. Inside, there is one bottle containing the refill liquid for electronic cigarettes, accompanied by two bottles that are empty.

**Country of origin:** United States

**Products were found and measures were taken also in:** Slovenia

**Type / number of model:** 6 mg of nicotine

**Brand:** Quickie

**Category:** Chemical products

**Alert submitted by:** Italy
Alert number: A12/0945/14
Product: Liquid for e-cigarettes
Name: Air Frankfort
Batch number / Barcode: Batch B/210313
Risk level: Serious
Risk type: Chemical

The products pose a chemical risk because: 1) it contains more than 1% of nicotine (wrongly labelled as 18 mg/ml, it actually contains 20.36 mg/ml) and does not contain an adequate safety label bearing risk-related indications, safety advice or a tactile danger warning. The product does not comply with Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations. 2) it contains nicotine (wrongly labelled as 6 mg/ml, it actually contains 6.34 mg/ml) and there is no adequate safety label bearing risk-related indications. The user therefore has no information on the dangers incurred when the product comes into contact with the skin or when inhaled.

Measures ordered by public authorities: Withdrawal of the product from the market
Description: Liquid for electronic cigarettes in a 10 ml bottle with screw top.
Country of origin: Poland
Products were found and measures were taken also in: France

Alert submitted by: Spain
Alert number: A12/1101/14

Product: Liquid for electronic cigarette

Name: Snake Oil

Batch number / Barcode: Unknown

Risk level: Serious

Risk type: Chemical

The packaging lacks a clear reference to the presence of nicotine (1.6%), the product is not equipped with a child-resistant fastening and does not contain an adequate safety label bearing risk-related indications, safety advice or a tactile danger warning. The user therefore has no information on the dangers incurred when the product comes into contact with the skin. The product does not comply with Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations.

Measures taken by economic operators: Withdrawal of the product from the market

Description: Liquid for electronic cigarettes in 10 ml and 30 ml bottles.

Country of origin: United Kingdom

Alert submitted by: France
Alert number: A12/1250/15

Product: Power supply for electronic cigarettes

Name: Power Adapter

Batch number / Barcode: 0609132557200

Risk level: Serious

Risk type: Electric shock

The plastic material holding the plug pins of the power supply is not sufficiently resistant to heat. The soldered conductors at the main contacts are not properly positioned or fixed and rely upon the soldering alone to maintain their position. These defects could lead to the user getting an electric shock. The product does not comply with the requirements of the Low Voltage Directive and the relevant European standard EN 60950.

Measures ordered by public authorities: Withdrawal of the product from the market

Description: Power supply for electronic cigarettes. The product comes in a white and red cardboard package.

Country of origin: China

Alert submitted by: Cyprus
Chemical: REACH, CLP, etc
Understanding REACH

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has an impact on most companies across the EU.

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users.

If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007.

How does REACH work?

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances.

[Source of information: Extract from ECHA website]
Figure 4: Registration deadlines

[Source of information: Extract from ECHA Guidance]
Registered substances

The data comes from registration dossiers submitted to ECHA by the date indicated as last update. The Total Tonnage Band is compiled from all the dossiers with two exceptions; any tonnages claimed confidential and any quantity used as an intermediate to produce a different chemical. The Total Tonnage band published does not necessarily reflect the registered tonnage band(s).

<table>
<thead>
<tr>
<th>Name</th>
<th>EC / List no.</th>
<th>CAS no.</th>
<th>Registration type</th>
<th>Submission type</th>
<th>Total tonnage band</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2-dimethylpropane-1,3-diol</td>
<td>204-781-0</td>
<td>126-30-7</td>
<td>Full</td>
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<td>100 000 - 1 000 000 tonnes per annum</td>
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<td>IUPAC name: propylene glycol</td>
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<td>Propane-1,2-diol</td>
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<td>57-55-6</td>
<td>Full</td>
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<td>100 000+ tonnes per annum</td>
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<tr>
<td>1-butoxypropan-2-ol</td>
<td>225-878-4</td>
<td>5131-56-8</td>
<td>Full</td>
<td></td>
<td>1 000+ tonnes per annum</td>
</tr>
</tbody>
</table>

[Source of information: Extract from ECHA website]
Nicotine

EC number: 200-199-3 | CAS number: 54-11-5

General information

Identification

Display Name: Nicotine

EC Number: 200-199-3

CAS Number: 54-11-5

Molecular formula: C10H14N2

Type of substance: mono-constituent substance

Origin: organic

Total tonnage band: 0 - 10 tonnes per annum

REACH

Registered set: full

Registrants / Suppliers of the substance

- Registrants / Suppliers - ACTIVE

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<tr>
<td>Nicobrand</td>
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<tr>
<td>Coleraine Londonderry United Kingdom</td>
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</tbody>
</table>

[Source of information: Extract from ECHA website]
SAFETY DATA SHEET (SDS) CHECKLIST

The Safety Data Sheet (SDS) Checklist has been developed in cooperation with the Forum for Exchange of Information on Enforcement (Forum). It has been designed from an inspector's point of view, to support the examination of the main body of a safety data sheet, compiled under REACH.

Compilers (suppliers) and recipients of safety data sheets can see from the different sections of the checklist template the types of questions that may be asked of them, related to their different roles. Compilers (suppliers), in particular, can see how thoroughly an inspector may examine the contents of different sections of the safety data sheet. However, please note that the checklist is not binding on inspectors. This checklist is being made public in order to support an overall objective, which is to improve the quality of safety data sheets in the supply chain.

[Source of information: Extract from ECHA website]
What is the interplay between CLP and TPD regarding the classification, labelling and packaging of e-liquids?

E-liquids for electronic cigarettes are regulated by the Tobacco Products Directive (TPD, Directive 2014/40/EU). The TPD requires Member States to ensure that electronic cigarettes and their refill containers are only placed on the market if they comply with the TPD and with all other relevant Union legislation (Article 20(1)), including the obligations under the CLP Regulation.

Under CLP, the classification, labelling and packaging of an e-liquid is the responsibility of the formulators or importers of the liquid. Under TPD, they must also submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. This notification should include the classification of the mixture in accordance with CLP.

The TPD sets its own labelling requirements for the unit packets of electronic cigarettes and refill containers (TPD Article 20(4)). In addition, the refill containers must also be labelled and packaged in accordance with CLP if the e-liquid is classified as hazardous. In that case, the unit packet must have a CLP label, with TPD-related information as supplemental. Overlapping information only needs to be indicated once: for example, the list of all ingredients required by TPD vs the list of ingredients contributing to classification under CLP.

It should be noted that the TPD provides that the nicotine content must not exceed 20 mg/ml and only ingredients that do not pose a risk to human health in heated or unheated forms may be used in the nicotine-containing liquid. However, other components of e-liquids have also been identified as hazardous and need to be considered in the classification and labelling of the e-liquid.

According to TPD, electronic cigarette devices and refill containers have to be child- and tamper-proof, protected against breakage and leakage and have to have a mechanism that ensures refilling without leakage (Article 20(3)g).

A refillable electronic cigarette device that is empty when placed on the market is not subject to the labelling obligations under CLP, as the hazards are dependent on the contents of the refill container.

**Modified Date:** 23/05/2017

**ID:** 1294

**Version:** 1.0

This answer has been agreed with national helpdesks.

[Source of information: Extract from ECHA website]
Tenth Adaptation to Technical Progress to CLP Regulation

<table>
<thead>
<tr>
<th>Index No</th>
<th>International Chemical Identification</th>
<th>EC No</th>
<th>CAS No</th>
<th>Classification</th>
<th>Labelling</th>
<th>Specific Conc. Limits, M-factors and ATE</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>614-001-00-4</td>
<td>nicotine (ISO); 1-[(2S)-1-methylpyrrolo-[2-yl]pyridine</td>
<td>200-193-3</td>
<td>54-11-5</td>
<td>Acute Tox. 2 H330</td>
<td>GHS06 H330</td>
<td>inhalation: ATE=0.19 mg/L (dusts or mist)</td>
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<td>Acute Tox. 2 H310</td>
<td>GHS09 H310</td>
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<td>Acute Tox. 2 H300</td>
<td>Dgr H300</td>
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<td>Aquatic Chronic 2 H411</td>
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</tbody>
</table>
Electrical and Electronic Equipment: RoHS2, LVD, EMC, etc
ANNEX II

Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials

- Lead (0.1 %)
- Mercury (0.1 %)
- Cadmium (0.01 %)
- Hexavalent chromium (0.1 %)
- Polybrominated biphenyls (PBB) (0.1 %)
- Polybrominated diphenyl ethers (PBDE) (0.1 %)

[Source of information: Extract from ROHS2]
Other Issues
## Standards catalogue

### ISO/TC 126/SC 3
Vape and vapour products

<table>
<thead>
<tr>
<th>Standard and/or project under the direct responsibility of ISO/TC 126/SC 3 Secretariat</th>
<th>Stage</th>
<th>ICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/DIS 20768 [Under development] Vapour products -- Routine analytical vaping machine -- Definitions and standard conditions</td>
<td>40.20</td>
<td>65.160</td>
</tr>
</tbody>
</table>
FCTC/COP6(9) Electronic nicotine delivery systems\(^1\) and electronic non-nicotine delivery systems\(^2\)

The Conference of the Parties (COP),

Recalling its decision FCTC/COP4(14) to request the Convention Secretariat to prepare jointly with WHO’s Tobacco Free Initiative a comprehensive report based on the experience of Parties on the matter of electronic nicotine delivery systems (ENDS) for consideration at the fifth session of the COP;

Recalling its decision FCTC/COP5(10) to request the Convention Secretariat to invite WHO to identify options for the prevention and control of ENDS and examine emerging evidence on the health impacts of the use of such electronic systems; and report on the outcome to the sixth session of the COP;

Recognizing that the Parties have adopted various regulatory strategies with respect to ENDS, such as an outright ban on their sale, the adoption of regulation similar to that applicable to the marketing of medicines, their control as tobacco products, or no control at all;

Noting that the report by WHO to the COP at its sixth session (document FCTC/COP/6/10 Rev.1) summarizes the public health debate and limited nature of the evidence on ENDS and presents both general objectives and specific regulatory options for consideration by Parties,

1. **WELCOMES** the report contained in document FCTC/COP/6/10 Rev.1 and invites Parties to take careful note of it;

2. **INVITES** Parties, when addressing the challenge posed by ENDS/ENNDS, to consider taking measures such as those referred to in document FCTC/COP/6/10 Rev.1 in order to achieve at least the following objectives, in accordance with national law:

   (a) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;

   (b) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;

   (c) prevent unproven health claims from being made about ENDS/ENNDS; and

   (d) protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry;

3. **INVITES** Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;

---

\(^1\) Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that vaporize a solution, which may include nicotine, or not, the user then inhales.

\(^2\) Electronic non-nicotine delivery systems (ENNDS)
EUROPEAN COMMISSION

Brussels, 20.5.2016
COM(2016) 269 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the potential risks to public health associated with the use of refillable electronic cigarettes
Thank You - Questions?

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