

Oxfordshire Trading Standards Service

ADVICE FOR RETAILERS IN RESPECT OF E-CIGARETTES - JULY 2022

- 1. Tobacco and Related Products Regulations 2016
- 2. Classification, Labelling and Packaging of Substances and Mixtures Regulation (EC) 1272/2008 (as amended and retained in UK Law)
- 3. The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
- 4. General Product Safety Regulations 2005

This document provides advice in respect of e-cigarettes and in particular disposable versions of these devices (aka "puff bars" or "vape pens") to ensure the products that you sell comply with the above-mentioned legislation.

1 - Legal requirements relating to the supply of e-cigarettes containing nicotine

Tobacco and Related Products Regulations 2016

Requirement for products to be notified to the MHRA prior to sale

You can only sell pre-filled disposable e-cigarettes or any other vaping liquid that contains nicotine which have been notified to the Medicines and Healthcare products Regulatory Authority (MHRA). When sourcing new supplies of any e-cigarette or e-liquid product, check that a compliant notification has been published in one of the Notified Product lists that can be found on the MHRA's website (https://cms.mhra.gov.uk/).

If you cannot find the product on the MHRA's website, ask your supplier to confirm that it has been published and provide details to enable you to confirm the products status. If a product has yet to achieve publication status, they may not supply it to you. Any stock offered for sale without said MHRA publication status is liable to seizure.

The Maximum Capacity & Strength of E-Cigarettes

Nicotine containing liquid which is presented for sale in a disposable electronic cigarette must not be in a volume exceeding 2ml. Sometimes these products do not have their capacity marked on them in ml but only specify a number of puffs. Such products are not legal to sell as they must have information about their capacity included on their packaging. However, if you already have stock that only provides the capacity in puffs (for example ELUX Legend 3500 and ELUX Max 4000 devices) then please note that any device stating that it contains more than 600 puffs is likely to be over-sized and liable for seizure if found on sale.

The maximum nicotine content of any type of e-cigarette be it a re-fillable or a disposable device is 2% (or 20mg/ml in liquid form). Devices with a nicotine content higher than 2%

cannot be sold in the UK. Please be aware that many manufacturers, for example Geek Bar, produce different versions of the same brand/flavour for both the EU/UK market where the limit is 2% and also for other markets (i.e. the USA) where the limit is higher-typically 5%. You must make sure that any stock you order, particularly if you are ordering online, is intended for supply to the UK market.

Labelling of E-Cigarettes

Each unit pack (individual e-cigarette) must include a leaflet which provides the following information. If the required leaflet information can fit on the pack and other labelling within the pack without loss of legibility to the consumer, a separate leaflet insert is not required. Such information should include:

- Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
- Contra-indications;
- Warnings for specific risk groups;
- Possible adverse effects:
- Addictiveness and toxicity;
- Contact details of the producer. The producer is any person who, in the course of a business, with a view to supplying the product for consumption in the United Kingdom or through the travel retail sector
 - o manufacturers the product
 - puts a name, trade mark or other distinguishing mark on it by which the person is held out to be its manufacturer or originator; or
 - o imports it into any part of the United Kingdom

Each unit pack (individual e-cigarette) and any container pack (packaging containing one or more unit pack) must include:

- A list of all ingredients contained in the product set out in descending order by weight;
- An indication of the nicotine content of the product and the delivery per dose;
- The batch number
- A recommendation to keep the product out of reach of children.
- A warning on the front and back surfaces of the pack stating: "This product contains nicotine which is a highly addictive substance". This wording must be used exactly as stated, occupy the greatest possible proportion of the space reserved for it and must cover 30% of the surface.

Please note: On a number of devices found during recent inspections this phrase is incorrectly given as "This product contains nicotine which is a highly addictive chemical" or "This product contains nicotine. Nicotine is a highly addictive chemical." These alternative wordings are not compliant with UK packaging regulations and products with this alternative wording must not be offered for sale. If they are then you will be committing an offence under the TRPR and the products are liable to be seized. If you are provided with stock bearing any warning that deviates from the above, approved, wording we recommend that you return it to your supplier immediately.

Packs may not contain anything that:

- Promotes the product by creating an erroneous impression about its characteristics, health effects, risks or emissions.
- Suggests the product is less harmful, has health benefits or environmental advantages.
- Resembles a food or a cosmetic product (though images of the flavourings are acceptable).
- Suggests economic advantage e.g. vouchers, offering discounts, free distribution, two-for-one, etc.

If you currently have stock that does not meet these requirements you <u>must</u> ensure that it does before it is offered for sale. This may be accomplished by the addition of stickers/labels to the products which provide the necessary information; by new packaging being provided or some other alternative method carried out by the Producer/Manufacturer/Importer, provided that it brings the product into compliance with the above. If this is not possible then we would recommend that you seek to return these items to your supplier.

CLP (classification, labelling and packaging) Regulation (CE) 1272/2008

Nicotine, or salts of nicotine are, in most but not all, cases the only hazardous substance contained in e-liquids. The labelling of the product therefore commonly depends on the concentration of nicotine or salts of nicotine it contains. The table below indicates the CLP hazard classification that might be required for mixtures containing different concentrations of nicotine and salts of nicotine. Where products contain concentrations above 0.3% the label should include the relevant pictogram, signal word, hazard statement and up to six of the precautionary statements. It is for the producer to assess which precautionary statements should be present. The packaging should also be fitted with a tactile warning triangle that complies with BS EN ISO 11683 PACKAGING - TACTILE WARNINGS OF DANGER - REQUIREMENTS

0.0% to 0.2% nicotine	0.3% to 1.6% nicotine	1.7% to 2.0% nicotine
Not classified	Harmful, Oral tox. Category 4	Toxic, Oral tox. Category 3
Signal Word: N/A	Signal Word: Warning	Signal Word: Danger
Hazard Pictogram: None		
Hazard Statement: N/A	Hazard Statement:	Hazard Statement:
	H302: Harmful if swallowed	H301: Toxic if swallowed
Recommended precautions that should be present on the label:		
It is not compulsory, but advised, to use the following: P101: If medical advice is needed, have product container or label to hand. P102: Keep out of reach of children. P405: Store locked up	P101: If medical advice is needed, have product container or label to hand. P102: Keep out of reach of children. P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P301 & P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P330: Rinse mouth. P501: Dispose of contents/container to	P101: If medical advice is needed, have product container or label to hand. P102: Keep out of reach of children. P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P301 & P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see on this label). P330: Rinse mouth. P405: Store locked up P501: Dispose of contents/container to

Other requirements for e-cigarettes

Manufacturers, Importers and Distributors of e-cigarettes also need to comply with the Restriction of Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (known as RoHS). These regulations limit the amount of certain hazardous substances in specific electrical and electronic equipment (EEE), of which e-cigarettes are included. They place obligations onto Manufacturers, Importers and Distributors of e-cigarette models. Details can be found here: https://www.gov.uk/guidance/rohs-compliance-and-guidance. This regulation is enforced by the Office for Product Safety and Standards, part of the Department for Business, Energy and Industrial Strategy (which includes Trading Standards). Items which do not comply with these regulations are liable for seizure by Trading Standards.

Distributors (anyone in the supply chain who is not a manufacturer or importer e.g. retailers and wholesalers) who makes EEE available on the market must ensure that the following are clearly identifiable on the products:

- The required "conformity mark". This is a CE mark or UKCA mark until 1st January 2022. After that date only the UKCA mark is allowed), and
- information identifying the manufacturer and importer (name, registered trade name or registered trademark and a single address),

If the information cannot fit on the product itself then the name and address can be given on the packaging or any accompanying documents. The conformity marking must be given on both. These products should now include a UK address following Brexit as the manufacturer/their authorised representative or the importer should be established in the UK and hold the relevant technical documentation to show compliance.

Please note Producers, Manufacturers, Importers and Distributors of e-cigarettes may also be subject to other legislative requirements, some of which are not enforced by Trading Standards and are not covered in this letter. This letter is not a comprehensive guide to all legislative requirements applicable to e-cigarettes.

2 - What happens if I sell products that don't comply with these regulations?

Products that are non-compliant with the above legislation are liable to be seized by Trading Standards. Where the devices are not over the UK limit on size and strength such products <u>might</u> be returned on the strict condition that the products are brought up to standard by the addition of labels/stickers or new packaging to bring them into compliance. However, if such items are seized then proof will be required of how this is to be done prior to any items being returned.

Please note that any items with a nicotine content above 20mg/ml (2%) or that contain more than 2ml of liquid will not be returned as these cannot be brought into compliance or returned into the UK supply chain.

If you are found offering non-compliant products for sale then this is likely to amount to a <u>criminal offence</u>. If prosecuted and found guilty, you could face an unlimited fine and even imprisonment. We therefore recommend that you ensure that any products you wish to sell meet the above requirements prior to stocking them.

www.oxfordshire.gov.uk/tradingstandards