



Health
Food Chain Safety
Environment

Guide for the trade of electronic cigarettes and e-liquids

**(valid from 11/07/2023 for wholesalers and from
11/01/2024 for retailers)**

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1 Introduction

This guide applies to e-cigarettes and refill containers with and without nicotine.

Electronic cigarette : a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank.

Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.

Refill container : a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette.

Refill container without nicotine : a receptacle that contains a nicotine-free containing liquid, which can be used to refill an electronic cigarette.

2 General provisions applicable to electronic cigarettes and e-liquids

The measures described in this chapter are derived from legal provisions applicable to "tobacco and tobacco-like products" and other legal provisions applicable to hazardous substances. The Federal Public Service for Public Health considers electronic cigarettes (and their components), e-liquids with nicotine (refill containers), e-liquids without nicotine and food flavorings intended for use in an electronic cigarette as "similar products" to tobacco products.

To facilitate understanding of this guide, these different products are referred to as e-cigarettes and e-liquids.

2.1 Sale

2.1.1 Sales Restrictions

E-cigarettes and e-liquids can be sold in automatic vending machines under certain conditions :

- ♦ The dispenser that contains e-cigarettes and e-liquids (or tobacco) must be located in a closed place accessible to consumers where the products are marketed simultaneously in the traditional way. It must be placed under supervision to prevent sale to minors.
- ♦ The distributor is locked. It can only be unlocked and activated by and for the benefit of a person 18 years of age or older.

From 9.12.2023, it will be prohibited to market e-cigarettes and e-liquids through automatic vending machines.

An exception is made for semi-automated sales in retail outlets where the age check is performed at the cash register and provided that the e-cigarettes and e-liquids are out of sight.

2.1.2 Minimum Age

E-cigarettes and e-liquids can only be sold to persons over the age of 18.

2.2 Advertising and Sponsorship

In Belgium, it is forbidden to advertise, promote and sponsor e-cigarettes and e-liquids. Advertising and sponsorship should be understood as any communication or action that directly or indirectly aims at promoting sales, whatever the place, the communication means, or the techniques used. Some examples of prohibited techniques (non-exhaustive list) :

- ♦ advertising posters ;
- ♦ price reductions and promotions ;
- ♦ specific highlighting of certain products or types of products in relation to others. The sales presentations of the products must be similar within the store ;

- ♦ highlighting the fact that these products are on sale. For example, the promotion of e-cigarettes and e-liquids without mention of any brand, both on the storefront and inside (as well as in leaflets and other promotional materials used by the store) ;
- ♦ sample offer ;
- ♦ ...

Exception : advertising in printed publications exclusively intended for professionals.

Thus, in a B2B context, only advertisements or posters (in leaflets/(online) magazines/websites) are allowed. That comes under advertising in printed publications, intended for people working in the sector. In addition, we also allow the advertising of an e-cigarette representative in a B2B context.

All other prohibited advertising techniques also apply to B2B retailers (including wholesalers).

2.3 Smoking in public spaces

Smoking e-cigarettes (with or without nicotine) is not authorized in enclosed public spaces. A no-smoking sign must be displayed at the entrance to and interior of enclosed public spaces.

It means that it is also prohibited to smoke inside the shops selling products for smokers. Users must first purchase the products and then go outside or to a smoking area if they wish to smoke.

Finally, the smoking area must meet certain conditions:

- it must be an enclosed space. The door must always be closed even when not in use ;
- it must not represent more than 25 % of the total surface area of the premises ;
- it must have a smoke extractor. The minimum flow rate is calculated according to the surface area of the smoke area (surface X 15m³/h) ;
- only drinks can be taken into the smoking area ;

- no services are offered: television, gambling, e-cigarette or e-liquid distributor, etc. ;
- the smoking area must not be a passageway to another space accessible to the public (e.g. toilets).

It is also prohibited to smoke in a vehicle in the presence of minors under the age of 18. The ban applies to all covered vehicles, i.e., where the vehicle is fully or partially enclosed by a roof and one or more doors and/or windows that can be opened. A contrario, the prohibition does not apply when the roof of the vehicle is completely folded.

2.4 Hazardous Substances

2.4.1 Classification of E-Liquids

E-liquids may not contain any hazardous substances which pose health risks. Any mix must be subject to a risk evaluation. This evaluation must be carried out by the responsible person, namely the person who sells these e-liquids and/or e-cigarettes. The responsible person can be the manufacturer, the importer and/or distributor.

The hazard evaluation pertains to the various substances (nicotine, flavourings, stabilisers, solvents, etc.) contained in the mix. It enables both the substances in the mix and one or more hazard categories to be classified. This classification of the substances and the mix must be indicated on the safety sheet (sections 2 and 3). For each hazard category, there are pictograms and hazard statements (also called "H statements") which must be displayed on the label (see also section 2.5, labelling). For each modification to the composition of the product, a new evaluation of the hazards is required, even if the name of the product does not change.

All the responsibilities of the various operators (manufacturers, importers, downstream users¹ and distributors) can be found on the website of the FPS Public Health :

<http://www.health.belgium.be/en/your-obligations-type-professionals>.

¹ Companies or individual workers who use chemical substances.

2.4.2 Reach

The REACH regulation (1907/2006) aims to protect the safety of people and the environment against the risks from chemical substances. Substances which are annually produced or imported into the EU in quantities higher than one tonne must be registered by the manufacturer or the importer with the European Chemicals Agency (ECHA). Unless it is registered, a substance may not be produced or sold.

This legislation applies for all e-liquids containing nicotine and/or hazardous substances (as soon as at least one tonne is manufactured or distributed annually).

The registration procedure and the criteria relating to the data can be found on the website of the ECHA : <https://www.echa.europa.eu>.

2.4.3 Product safety

For risks not covered by the previously mentioned laws, electronic cigarettes and e-liquids fall under the scope of the Code of Economic Law, Book IX on the safety of products and services : <https://economie.fgov.be/en> > Home > Themes > Quality and safety > Safety of products and services > Regulations.

The website of the FPS Economy includes the relevant regulations, useful information (e.g. on obligations for producers) and the document entitled "*Questions et réponses sur l'interprétation des dispositions relatives à la sécurité des produits et des services reprises dans le Code de droit économique*" (Questions and answers on the interpretation of provisions about the safety of products and services in the Code of Economic Law - only available in French and Dutch).

The producer must fulfil the following obligations :

- ♦ placing only safe products on the market ;
- ♦ informing the consumer of the risks posed by a product, by displaying the necessary user instructions and warnings ;
- ♦ displaying his name and contact details as well as the product reference (or the batch to which it belongs) on his products or their packaging ;
- ♦ taking measures to stay informed about the risks associated with the supplied products and taking action to prevent these risks ;

- ♦ notifying immediately the Central Contact Point if a marketed product poses a risk to the consumer ;
- ♦ taking part in the measures taken by the authorities to prevent risks associated with the supplied products.

The producer is defined by the Code of Economic Law as :

- ♦ The product manufacturer or the service provider, when he is established in a Member State, and any other person presenting himself as the manufacturer by displaying to the product his name, trade mark or
other distinctive mark, or the person who reconditions the product, and any other person who presents himself as the service provider;
- ♦ the representative of the product manufacturer or of the service provider, when these are not established in a Member State, or, if there is no representative established in a Member State, the product importer or the service distributor ;
- ♦ other professionals in the marketing or service delivery chain, insofar as their activities may affect the safety properties of a marketed product ;
- ♦ the employer who manufactures products for use in his own business.

2.4.4 Poison Control Centre

If an e-liquid contains hazardous substances and/or nicotine, the manufacturer must notify the Poison Control Centre of the exact composition.

The procedure is explained at <http://www.centreantipoisons.be/entreprises> (only available in French and Dutch)

The form to be completed for the notification to the Poison Control Centre can be found at the following link :

<https://www.centreantipoisons.be/entreprises/comment-d-clarer/d-claration-des-m-langes-class-s-comme-dangereux> (only available in French and Dutch)

2.5 Labelling

All indications displayed on the packaging or the label must be clearly visible, legible and indelible.

2.5.1 Electronic waste

The electric and electronic elements of an electronic cigarette are hazardous waste, which are not part of residual waste. This is designated by the official pictogram :



This pictogram is usually displayed on the product itself.

If the product is too small, the pictogram can be displayed on the packaging, in the instruction leaflet, and indicated on the guarantee certificate.

More information can be found in the Royal Decree of 17 March 2013 for the restriction of the use of certain hazardous substances in electrical and electronic equipment. This Royal Decree is available at the site :

<http://www.ejustice.just.fgov.be> (only available in French and Dutch)

2.5.2 Hazardous Substances

All mixes containing hazardous substances must be classified in one or more hazard categories, e.g. :

"acute toxicity" or "awareness" (allergens). The hazards pertaining to an e-liquid must be indicated on the label using :

- ♦ the relevant official pictograms (min. 1 cm square) ;
e.g.: nicotine is hazardous (fatal) to health and to the environment (pictograms) ;
- ♦ hazard or H statements ;
e.g.: toxic in contact with skin
- ♦ precautionary measures or statements ;
e.g.: avoid contact with the eyes, skin or clothing

- ♦ a hazard triangle which is detectable by touch for the blind and visually-impaired (if the pictogram representing the death's head or the exclamation mark is displayed).

At the very least, this information must be indicated in the three national languages (French, Dutch and German), both on the e-liquid container and on the (exterior) packaging. Information in a given language must be indicated on the same side.

If the container is too small, e.g. 10 ml, the manufacturer can also indicate the mandatory information on the booklet attached to the e-liquid packaging. The name of the product, the quantity of the e-liquid, the hazard pictogram, the warning indication and the contact details of the responsible company must be indicated on the exterior (visible) side of the booklet. The booklet itself must contain all the remaining information, classified per language.

The control of the prepackaged volume of e-liquids and filling instruments is the responsibility of the FPS Economy.

2.5.3 Electromagnetic compatibility

Electronic cigarettes fall within the scope of the Electromagnetic Compatibility Directive, transposed into Belgian law by the Royal Decree of 1 December 2016 on electromagnetic compatibility. According to this directive, the following indications must be displayed on the apparatus or, where the size or nature of the apparatus does not allow it, on the packaging and/or in a document accompanying the apparatus :

- ♦ CE marking ;
- ♦ manufacturer's name, registered trade name or registered trade mark and postal address ;
- ♦ when the products are imported from a third country into the EU market: importer's name, registered trade name or registered trade mark and postal address ;
- ♦ type, batch or serial number, or other element allowing their identification.

These indications must be accompanied by instructions and information concerning the use of the apparatus. These instructions and information must be

written at least in French and/or Dutch and/or German, depending on the language region in which the apparatus is made available on the market.

3 Specific provisions applicable to electronic cigarettes and e-liquids

3.1 Notification

All electronic cigarettes and e-liquids which are marketed in Belgium, must be subject to a prior notification (six months before placing on the market). This is the manufacturer's or importer's responsibility if the former does not have a registered office in Belgium and has not notified of the product.

To notify the Belgian authorities, the European EUCEG system must be used. The complete procedure can be found at <http://ec.europa.eu/health/euceg>.

A fee of EUR 200 must be paid for each product in the notification file. The competent service will send an invoice before proceeding to data verification. After payment, the competent service will verify that the submitted information about the notified products complies with the legal requirements.

If the registered information is no longer up to date due to a change to the product, the modified or additional information must be submitted to the service. A fee of EUR 100 must be paid for a substantial modification in the notification file.

All information about the notification procedure can be found at the following website : <https://www.health.belgium.be/en/specific-regulations-electronic-cigarettes-0>

Products whose notification is compliant with Belgian legislation (data correctly entered and payment made) are placed on a positive list and may be marketed.

This list is regularly updated on our website :

<https://www.health.belgium.be/en/positive-list-e-cigarette>

For any information about notification, please contact enottab@health.fgov.be.

3.2 Composition

3.2.1 General regulations for nicotine-containing and nicotine-free e-cigarettes and refill containers

A refill or reservoir of an e-cigarette may contain a maximum of 2 ml. All refills shall be unbreakable and equipped with a child-resistant device. They shall comply with the ISO 8317 standard.

It is prohibited to place electronic cigarettes on the market which have attractive features that are not useful for operating the device.

Some additives are not allowed in e-liquids and e-cigarettes :

- ♦ vitamins or other additives which create the impression that the e-cigarette has beneficial health effects or that the health risks it pose were reduced ;
CBD, for instance, is prohibited in e-liquids.
- ♦ caffeine, taurine and other stimulant additives associated with energy and vitality ;
- ♦ additives which aim at colouring the emissions of vapor ;
- ♦ additives which have carcinogenic, mutagenic² and reprotoxic properties³ (without needing combustion) ;
- ♦ additives that facilitate the inhalation or the intake of nicotine.

3.2.2 Specific regulations for nicotine-containing refill containers

Oral intake of nicotine in liquid form can be fatal, especially in young children. To limit this risk, precautionary measures are applicable to nicotine-containing e-liquids :

- ♦ the maximum authorized concentration is 20 mg of nicotine per ml ;

² Substances that can damage genetic material and that, in combination with other substances, can be carcinogenic.

³ Substances that have a harmful effect on fertility but can also harm the development of the unborn child and can cause birth defects.

- ♦ the refill container shall not exceed 10 ml ;
- ♦ electronic cigarettes deliver consistent doses of nicotine under normal use.

3.3 Labelling

3.3.1 Packaging

The labelling of e-cigarettes and e-liquids shall contain the following information in the three national languages :

- ♦ all the ingredients contained in the product in descending order of weight ;

The FPS Health requires at least the following cumulative criteria :

- a. The flavour must be characterized in a neutral way (not promotional) by mentioning the main taste(s) that compose it (e.g.: strawberry flavour).
 - b. All additives exceeding 0.1 % shall be mentioned.
 - c. Allergens shall be mentioned even at a concentration lower than 0.1 % (e.g. limonene).
- ♦ an indication of the nicotine content of the product and of the quantity delivered per dose ;
 - ♦ a batch number preceded by the word “lot” ;
 - ♦ a recommendation that the product be kept out of the reach of children (in the form of text or a logo) ;
 - ♦ the product ID issued by the notification system.

The labelling of nicotine-containing products (e-cigarettes and e-liquids) bears the following health warning on the two largest surfaces :

**“La nicotine contenue dans ce produit crée une forte dépendance.
Son utilisation par les non-fumeurs n’est pas recommandée.**

**Dit product bevat de zeer verslavende stof nicotine. Het gebruik
ervan wordt afgeraden voor niet-rokers.**

**Dieses Produkt enthält Nikotin: einen Stoff, der sehr stark
abhängig macht. Es wird nicht für den Gebrauch durch
Nichtraucher empfohlen.”**

The labelling of nicotine-free e-liquids bears the following health warning on the two largest surfaces :

**“Ce produit nuit à votre santé. Son utilisation par les non-fumeurs
n’est pas recommandée.**

**Dit product schaadt uw gezondheid. Het gebruik ervan wordt
afgeraden voor niet-rokers.**

**Dieses produkt schädigt Ihre Gesundheit. Es wird nicht für den
Gebrauch durch Nichtraucher empfohlen.”**

These two warnings shall be printed in the three national languages and shall cover 35 % of the surface intended for them. They shall also be framed with a 1 mm wide black border within the area reserved for them. Each language is printed on a new line.

The packaging units and outer packaging of e-cigarettes and e-liquids shall not contain any element or mechanism which :

- ♦ suggests that a given e-cigarette or refill container is less harmful than others or is intended to reduce the effect of certain harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural or biological properties or any other beneficial effects on health or lifestyle ;

- ♦ resembles a food or cosmetic product ;
- ♦ suggests that a given e-cigarette or refill container is more easily biodegradable or has other environmental benefits ;
- ♦ suggests economic benefits by means of printed vouchers, discount offers, free distribution, “two for the price of one” promotions or similar offers.

The suggestion of a taste, aroma or flavouring can be indicated only with one single word in weighted alphabetical letters using Helvetica characters, normal and regular, black or white, with font size not larger than 10.

The brand and sub-brand appearing on the packaging unit and outer packaging shall be identical to those entered into the notification system.

E-liquids are provided with an expiry date. The e-liquids whose expiry date has passed may no longer be placed on the market.

3.3.2 Leaflet

All packaging units of e-cigarettes and e-liquids shall include a leaflet. This leaflet must contain the following information in the three national languages :

- ♦ instructions for the use and storage of the product, including a note indicating that the use of the product is not recommended for young people and non-smokers ;
- ♦ contraindications ;
- ♦ warnings for specific risk groups ;
- ♦ possible side effects ;
- ♦ addictiveness and toxicity ;
- ♦ the contact details of the manufacturer or importer, and of a natural or legal person in the European Union ;
- ♦ the number of the Anti-Poisons Centre.

Labelling of refillable e-cigarettes and their components

When an electronic cigarette or one of its components is placed on the market without containing liquid, the labelling can be simplified and shall only include, in the three languages :

- the mention of a batch (or serial) number ;
- a recommendation on the packaging that the product be kept out of the reach of children ;
- the product ID ;
- the leaflet.

3.4 Distance selling

Distance selling to consumers and distance purchasing by consumers of electronic cigarettes and e-liquids are prohibited. Practically, it means that selling and buying over the internet are prohibited.

By way of derogation, cross-border distance selling from Belgium is allowed if the legislation of the Member State of destination so permits.

3.5 Infringements

E-cigarettes and e-liquids which do not comply with these specific regulations are considered harmful according to legislation and are consequently prohibited. Prohibited e-cigarettes and e-liquids may be withdrawn from the market during an inspection.

4 For further information

- ◆ www.health.belgium.be > Santé > Produits à fumer et e-cigarettes > Informations et réglementations communes et réglementation spécifique aux cigarettes électroniques (only in French or Dutch)
- ◆ About general product safety : <https://economie.fgov.be/en> > Home > Themes > Quality & Safety > Safety of products and services > Regulations

About electromagnetic compatibility (only in French or Dutch) : <https://economie.fgov.be/fr> > Accueil > Thèmes > Energie > Sources d'énergie > Électricité > Sécurité des produits électriques > Compatibilité électromagnétique

For questions related to these two points : economie.fgov.be
- ◆ For questions related to ROHS, CLP, REACH, the Anti-Poisons Centre: www.helpdeskclp.be or info@environment.belgium.be
- ◆ For questions related to the notification of products : enottab@health.fgov.be
- ◆ For all other questions : apf.inspec@health.fgov.be
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