

E-CIGARETTE WORKING GROUP DISCUSSION PAPER ON SUBMISSION OF NOTIFICATIONS UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU

CHAPTER 2 – PRODUCT TYPE

INTRODUCTION

Article 20(2) of Directive 2014/40/EU [TPD] places an obligation on the manufacturers and importers of electronic cigarettes to submit a notification to the competent authorities of the Member State of such products they intend to market.

The European Commission has established a common format for the notification of these products within Commission Implementing Decision 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. The submission format is set out in the annex to that Decision and the product type is required in section 3 of that annex.

WHAT IS REQUIRED

Article 20(2) of the TPD requires the manufacturer or importer of an electronic cigarette or refill container to submit a notification for all products already on the market on 20 May 2016 or intended to be placed on the market after that date.

INFORMATION TO BE REPORTED

For the response to the field '**Product_Type**' in Section 3.A of the Annex, the following response options could be considered (please note that the fields to be completed will vary depending on product type selected):

	Product type
1	Electronic cigarette – Disposable
2	Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination). <i>Any rechargeable which can also be used as a refillable should be reported under the refillable category</i>
3	Electronic cigarette – Rechargeable, device only. <i>Any rechargeable which can also be used as a refillable should be reported under the refillable category</i>
4	Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination)
5	Electronic cigarette – Refillable, device only
6	Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge
7	Refill container/cartridge containing e-liquid
8	Individual part of electronic cigarette capable of containing e-liquid
9	Other

Explanatory note

General considerations

From the definition of electronic cigarette and refill container it follows that the TPD is only applicable to electronic cigarettes that contain nicotine or can be used with a nicotine-containing liquid and refill containers that contain a nicotine-containing liquid.

The TPD is therefore not applicable to disposable electronic cigarettes that contain nicotine-free liquid or to cartridges that contain nicotine-free liquid. Furthermore, an electronic cigarette can only be brought on the market in the form of a **i)** disposable electronic cigarette, **ii)** rechargeable electronic cigarette to be recharged with single use cartridges, or **iii)** refillable electronic cigarette to be refilled by means of a refill container and possessing a tank. Because cartridges may only be suitable for single use, they cannot be refillable.

Although refillable electronic cigarette devices are generally placed on the market without liquid, the device falls within the scope of the TPD since it can be used with liquid containing nicotine. Individual parts of the electronic cigarette sold separately also fall within the scope of the TPD. These only need to be notified if these are essential elements of the electronic cigarette **and** capable of containing nicotine. This would include the tank, atomiser or cartridge but would exclude other components such as replacement batteries or mouthpieces. More generic parts such as washers, O-rings and screws, which are necessary for the functioning of the device but are not characteristic elements of electronic cigarettes, could also be deemed to fall outside the scope of the reporting obligations foreseen under the TPD.

In order to determine whether an e-cigarette can be placed on the market, the manufacturer/importer should carefully verify whether it is capable of falling under the relevant definitions provided for in the Directive, and of complying with all of the quality and safety provisions under Article 20. When notifying products, manufacturers/importers should select the appropriate 'product type' from the list above. If products are not capable of meeting the criteria set out in the Directive, they cannot be deemed to be compliant. Where it is unclear how products are capable of fully complying with all provisions of Article 20, in particular the technical standards for the refill mechanism set out in Commission Implementing Decision 2016/586, the notifier should explain how the item is compliant in their notification and be able to respond to requests for justification from the competent authority.

Specific notes

1. Electronic cigarette – Disposable

This category applies to prefilled electronic cigarette products intended for single use only (not refillable or rechargeable).

2. Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination)

This category applies to rechargeable electronic cigarette devices that are placed on the market as a single unit together with one single use cartridge containing one type of e-liquid. The device may subsequently be recharged with cartridges of the same type or other types, purchased separately.

Where a product consists of two notified products, for example a rechargeable e-cigarette sold with a single use cartridge where the empty e-cigarette product and the cartridge have both been notified, then **if there has been no rebranding** the composite product does not need to be notified. It will only be accepted that rebranding has not occurred where the brand names of the individual component products are clear so that retailers and consumers can access the published notification information should they choose to do so.

In addition, we consider that any rechargeable product which is also capable of being used as a refillable should be reported under the refillable category.

4. Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination)

This category applies to refillable electronic cigarette devices that are placed on the market with one specific type of refill container containing one type of e-liquid. The device may subsequently be refilled from a refill container, purchased separately.

6. Kit – Pack containing two or more products including different e-cigarette devices and/or different refill containers/cartridges

Where a kit consists of two or more notified products, for example a rechargeable e-cigarette sold with a selection of flavour or strength cartridges where the empty e-cigarette product and each cartridge refill container have all been individually notified, then **if there has been no rebranding** the kit does not need to be notified. It will only be accepted that rebranding has not occurred where the brand names of the individual component products are clear so that retailers and consumers can access the published notification information should they choose to do so. This is only possible where each individual component has been notified.

8. Individual part of electronic cigarette capable of containing e-liquid

This category applies to characteristic parts of electronic cigarettes as described in the general considerations section. In their notifications, submitters should provide the name and a clear description of the product/part if this 'product type' is selected.

9. Other

This category applies to electronic cigarettes and refill containers falling outside the listed categories. In their notifications, submitters should provide the name and a clear description of the product/part if this 'product type' is selected.

Note on reporting sales data:

Where separate notifications have not been submitted for kits or composite products where the components have been submitted individually, sales data for the combination also need to be submitted. This can be achieved, for example by including in the sales data for one of the components as statement that 'this product is also sold in combination with X product in a combination pack, and sales volume for this composite product are XXX'.