

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

## CHAPTER 4 – DOSE OF NICOTINE DELIVERED & UPTAKE AND CONSISTENCY OF DOSE

### **INTRODUCTION**

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

Article 20(2)(d) of the TPD requires the notification to include information on the nicotine dose and uptake when consumed under normal or reasonably foreseen conditions.

Article 20(3)(f) places an obligation on Member States to ensure that the dose is delivered by an e-cigarette at a consistent level under normal conditions of use.

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 information required on nicotine dose and uptake is set out in section 6 of the annex.

### **WHAT IS REQUIRED**

The TPD requires those submitting to communicate the level of nicotine uptake when the product is used under normal and reasonably foreseeable conditions, and to describe the measurement methods used to assess this.

As full clinical testing will not be required, alternative methods to determine uptake, such as measurement of the weight of nicotine in the e-cigarette vapour, would be considered adequate.

The method used should be carried out in accordance with the expected use of the product and the usage instructions in the product's user leaflet and a standard puff regime, once available (reference should then be made to this standard).

In the absence of standard methodology, the description should contain information capable of enabling the regulator to understand and be in a position to duplicate the test, if necessary.

The TPD also requires Member states to ensure that those submitting notifications have determined the consistency of the dose delivered. This could be measured and expressed e.g. as nicotine content per puff (where the puff regime is accurately described) or per pack as appropriate. The data reported should be determined over a set number of such puffs (e.g. 10).

In the absence of standard methodology, the description should contain information capable of enabling the regulator to understand and be in a position to duplicate the test, if necessary.

## **HOW SHOULD TESTING BE UNDERTAKEN**

Where a product is to be placed on the market as a single e-cigarette unit sold together in one combination, this should be tested and notified as a unit (the EC-ID will be reported with the notification). Where the product is sold containing a range of strengths of nicotine-containing liquid, it may be sufficient to test the highest strength only. In these cases, the results for the liquid strength already tested should be submitted together with a calculation of the expected dose delivery at the strength being notified and a clear justification as to why the previous results are applicable.

## **E-CIGARETTES**

Where products are supplied separately, companies should endeavour to test devices and components that they wish to notify in combination with other product(s) from their own portfolio of products. Where this is not possible (because the company does not supply all components to the market) testing should be undertaken with the product that the manufacturer/importer estimates to be most commonly used in combination with the product being notified or to pose the highest potential risk to the consumer. Where known, the EC-ID for the additional product should be stated. If not known, the brand name and Member States in which the product is available should be provided. If external power supplies are used, they should mimic the performance of the type of e-cigarette battery the product is designed to operate with.

Where a kit is marketed which contains more than one combination of items, all combinations of the included items that could reasonably be expected to result in a different nicotine delivery should usually be tested and the results should be submitted separately under the relevant section of the notification. However, where a combination could reasonably be expected to have the same nicotine delivery as a tested combination, the results for the combination already tested should be submitted together with a clear justification as to why these are also applicable for the current notification.

Where a product includes a modular device with the ability to vary the power level in use testing should normally be undertaken at the highest level at which the device can operate optimally and the data reported for that level only. Submitters should be in a position to clearly justify the choice if requested.

## **E-LIQUIDS**

Since the delivery of nicotine depends to a large extent on the device used, it may not be necessary to test all e-liquid products. Unless the composition of the product suggests that the nicotine content may not be uniformly distributed throughout the liquid, the results of a sample flavour product from the range could be submitted for subsequent flavours, or a simple analysis of the nicotine content per ml of liquid will suffice. If there is a reasonable likelihood that the nicotine content is not uniformly distributed, then tests should be performed as described in the sections above using a device that is likely to be commonly used with the e-liquid.