

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

CHAPTER 3 – EMISSIONS FROM ELECTRONIC CIGARETTES

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 States of such products they intend to market.

Article 20(2)(b) of the TPD requires the notification to include a list of the emissions which result from the use of the product.

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 emissions and the information required are set out in section 5 of the annex.

WHAT IS REQUIRED

The TPD requires emissions from all notified products to be included within the submission. The testing should be carried out in accordance with the expected use of the product and the usage instructions as provided in the product's user leaflet, or by a standardised puff regime once available (reference should then be made to this standard in the submission).

A list of key emissions which are expected to be reported for any notified product is set out in the table below. This list is not exhaustive and other emissions may also need to be included in the notification.

KEY EMISSIONS TO BE REPORTED

Under section 5 on emissions, information on the following key emissions should always be submitted:

COMPOUND	CAS NUMBER
Acetaldehyde	75-07-0
Acrolein	107-02-8
Formaldehyde	50-00-0

Depending on the particular device / liquid combination and the toxicological assessment, information on other key emissions may need to be provided. These include diethylene glycol, ethylene glycol, diacetyl, pentane 2,3 dione and tobacco-specific nitrosamines.

Depending on the material composition of the hardware, information on the following metal emissions should be provided:

METAL	CAS NUMBER
Aluminium	7429-90-5
Chromium	7440-47-3
Iron	7439-89-6
Nickel	7440-02-0
Tin	7440-31-5

If other metals such as lead and mercury are present in the hardware, submitters should include information on these.

HOW SHOULD TESTING BE UNDERTAKEN

HARDWARE

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 clear justification as to why these are also applicable for the current notification.

Where products are supplied separately, companies should endeavour to test devices, refill containers and cartridges that they wish to notify in combination with other product(s) from their own portfolio. 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, emissions data should be included in the notification for each of the items or combinations. However, it may not be necessary to test all combinations. The combination expected to produce the maximum emissions should be tested (without prejudice to the section on flavours below). Results obtained can be used to support combinations which are likely to produce a lesser level of emissions, but submitters should clearly justify the appropriateness of the data submitted.

Similarly (without prejudice to the section on flavours below) a range of product options will not always require testing of each variant. Companies may rely on data generated from a representative sample and justify their choice. Where a combination could justifiably be expected to have the same emissions as a tested combination, the results for the combination tested should be submitted together with a clear justification as to why the results are applicable.

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 data reported for that level only. Submitters should clearly justify the power level tested.

FLAVOURS

Emissions testing should be carried out at least once on each flavour and on each combination of flavours. It may not be necessary to test all flavours or combinations of flavours with all kits or devices. Companies may be able to rely on data generated on a subset of flavour or product options on a risk based basis. Provided the flavour or flavour combination has been tested in one presentation, the data generated could be used to support other notifications, provided the emissions can justifiably be expected to be similar. Clear justification should be provided for the choice of subset.

WHAT SHOULD BE REPORTED

The annex to the Commission Implementing Decision sets out the data which should be reported in the notification.

Where multiple emissions have been measured, the following information is required to be completed for each of these:

- The name of the emission;
- The quantity produced during use based on the measurement method used;
- A description of the test method used, including reference to a recognised approved standard, when available.

One of the following must be reported for each emission identified:

- The Chemical Abstracts Service number (CAS) of the compound (where one exists)
- The International Union of Pure and Applied Chemistry (IUPAC) name should a CAS number not exist

For all submissions, the test methods used should be included within the submission or reference made to a recognised standard test method, once available. In the absence of standard methodology, the description of the test methodology should contain information capable of enabling the regulator to understand and be in a position to duplicate the emission test if necessary.