

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

CHAPTER 1 – SUBMISSION 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 submission type is required in section 2 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.

A new notification is required for each substantial modification of the product.

INFORMATION TO BE REPORTED

Value	Name
1	Notification of a new product (6 months advance notice, new EC-ID number).
2	Substantial modification of information on a previously notified product (6 months advance notice, new EC-ID number with a link to the previous EC-ID)
3	Update of existing product – addition of information in section 3.B on product format and/or Member State(s) notified (new EC-ID version . <i>To note: the 6 months advance notice obligation applies for all additional Member States added</i>)
4	Update of existing product – withdrawal of information in section 3.B on product format and/or Member State(s) notified (new EC-ID version . <i>To note: This may include withdrawal of a product or a product format in all or certain Member State(s)</i>)
5	Update of existing product – other information (new EC-ID version)
6	Updates to information to be submitted annually under Article 20(7) TPD such as sales data. (new EC-ID version)
7	Correction (new EC-ID version)

Submission types 1 & 2 - new notifications or substantial modifications to previously notified products:

Submission type 1

- This submission type should be chosen when notifying all new e-cigarettes and refill container products not already on the market on 20 May 2016. Such a notification must be made at least 6 months before the intended date of placing on the market. Member States may apply transitional arrangements for products to be launched in the period up to 20 November 2016.

This submission type should also be chosen for all e-cigarettes and refill containers already on the market on 20 May 2016. This notification must be made by 20 November 2016.

Submission type 2

- This submission type should be chosen when a substantial modification is made to a previously notified product. This notification must be made at least 6 months before the intended date of placing on the market. A substantial modification is a change to the product that may have an effect on the human body. Such changes include one or more of the following:
 - any change to the qualitative or quantitative composition of the nicotine-containing liquid
 - any change to the volume of a refill container, tank or cartridge
 - any change to the composition, design or power output of a device which would be likely to affect emissions

Submission types 3, 4 & 5 - Manufacturers and importers should update their notification and choose an appropriate submission type from the list below when doing so:

Submission type 3

- (*This concerns the **addition** of information in Section 3.B only.*) This submission type should be chosen if an existing product is to be launched in one or more additional Member States. This update must be made at least 6 months before the intended date of placing on the market in the Member State(s) concerned. This submission type should also be chosen if a new product format is being added in one or more Member States.

Submission type 4

- (*This concerns the **withdrawal** of information in Section 3.B only.*) This submission type should be chosen if a product, or an individual product format, is to be withdrawn from the market in one or more Member States. This update should be made promptly to ensure proper market oversight, e.g. that ongoing fees are not charged for the notification by Member States.

Submission type 5

- *(This concerns updates to information in sections other than the addition of information in Section 3.B.)* This submission type should be chosen when updates to sections other than Section 3.B are required but the change is not a substantial modification (see submission type 2 above).

Submission type 6 – updates to information to be submitted annually under Article 20(7) TPD

Member States may oblige manufacturers and importers to submit the annual information required under Article 20(7) of the TPD via the EU-CEG. Submission type 6 should be chosen when doing so. This information includes annual reports on sales volume, by brand name and type of product and the mode of sale of the products. Where available, this report should also include information on the main types of current users and the preferences of various consumer groups including young people and non-smokers and executive summaries of any market surveys carried out on these.

Submission type 7 – Correction

This submission type should be chosen in order to rectify errors in previously submitted information (such as typos, spelling corrections etc.)