



Brussels, **XXX**
[...] (2015) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of XXX

**establishing a common format for the notification of electronic cigarettes and refill
containers**

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THE EUROPEAN COMMISSION,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC¹, and in particular Article 20 (13) thereof,

Whereas:

- (1) Directive 2014/40/EU provides that manufacturers and importers of electronic cigarettes and refill containers are to submit to the competent authorities of the Member States concerned a notification of any such products which they intend to place on the market or which are already placed on the market on 20 May 2016. The information should be submitted six months before the intended placing on the market of new or substantially modified products. The format for that notification should be laid down.
- (2) The experience gained and the knowledge acquired with existing formats for the reporting of tobacco ingredients, where relevant, should be taken into account when developing the format.
- (3) A common electronic notification format for submission of information on electronic cigarettes and refill containers should allow Member States and the Commission to compare, analyse and draw conclusions from the information received. The data will also provide a basis for assessing health impacts associated with these products.
- (4) A common electronic entry gate for submission of data is essential to ensure uniform application of the notification obligations set out in Directive 2014/40/EU. In particular, a common entry gate facilitates and harmonises the submission of data from the manufacturer or importer to the Member States. Streamlining the submission process also reduces administrative burden for manufacturers, importers and national regulators and facilitates comparison of data.
- (5) The common entry gate should foresee tools for submission of information which are adequate both for companies which have comprehensive IT solutions in place (system to system submissions) and for companies which have no such solutions, in particular small and medium sized companies.
- (6) Member States should be free to make the tools for submission of information laid down in this Decision available for submission of information required under Article

¹ OJ L 127, 29.04.2014, p. 1.

20(7) of Directive 2014/40/EU and should encourage updates to be submitted during the first half of the subsequent calendar year in order to ensure comparability within the Union. The tools could also facilitate submission of other information on electronic cigarettes and refill containers pursuant to Article 20.

- (7) When resubmitting data, including correcting errors in an earlier submission, the information should be provided through the common entry gate indicating which previous data set should be replaced or deleted. The previously submitted information should remain available, but should be marked as obsolete where appropriate.
- (8) In order to ensure the quality and comparability of data submitted, Member States should, where applicable, encourage manufacturers and importers to use agreed standards or testing methods. In the absence of agreed Union or international standards or testing methods, manufacturers and importers should clearly describe in their notifications the measurement methods used and should ensure that they are reproducible.
- (9) In order to limit the administrative burden and ensure comparability between reported data, Member States should encourage manufacturers and importers to select compatible items when testing components of electronic cigarettes and refill containers placed on the market as separate items.
- (10) Whilst the full responsibility for gathering, verifying, analysing, storing and disseminating the data collected in accordance with this Decision lies with the Member States, they should have the possibility to store the data submitted to them at Commission facilities. The service offered by the Commission should provide Member States with technical tools to facilitate compliance with their obligations under Article 20 of Directive 2014/40/EU. The Commission will develop a standard service level agreement for this purpose. With the agreement of Member States, the Commission should keep an off-line copy of the data submitted through the common entry gate for the purpose of applying Directive 2014/40/EU.
- (11) Member States should encourage manufacturers and importers to provide up-to-date toxicology data if new data become available.
- (12) When submitting information on products with the same composition and design, manufacturers and importers should to the extent possible, use the same identification number, regardless of brand and subtype or whether they are placed on the market in one or more Member States.
- (13) It is appropriate to lay down rules concerning the treatment of confidential data by the Commission in order to ensure the greatest possible transparency of product information for the general public, whilst ensuring that due account is taken of trade secrets. The legitimate expectation of consumers to have access to adequate information on the content of products they intend to consume should be weighed against manufacturers' interests of protecting recipes of their products. Having regard to those competing interests, data that could reveal ingredients used in small quantities in specific products should, in principle, be kept confidential.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision establishes a common format for the notification of information on electronic cigarettes and refill containers.

Article 2

Format for notification

1. Member States shall ensure that manufacturers and importers of electronic cigarettes and refill containers submit information referred to in Article 20(2) of Directive 2014/40/EU, including modifications and withdrawal from the market, in accordance with the format provided for in the Annex.
2. Member States shall ensure that manufacturers and importers of electronic cigarettes and refill containers submit the information referred to in paragraph 1 by means of a common entry gate for data submission.

Article 3

Storage of data

Member States shall be entitled to use data storage services offered by the Commission to comply with their obligations under Article 20(2) of Directive 2014/40/EU provided they have signed a service level agreement with the Commission.

Article 4

Identification number of the data submitter

Before submitting information to Member States for the first time pursuant to this Decision, the manufacturer or importer shall obtain an identification number generated from the common entry gate. In its application for the identification number, the manufacturer or importer shall provide the Commission with a certificate by a competent national authority that the manufacturer or importer is carrying out commercial activities in the area of electronic cigarettes, including a description of its main activities and an English translation thereof where needed. The manufacturer or importer shall use the identification number for all subsequent submissions and in all subsequent correspondence.

Article 5

Identification number of the product

1. Based on the identification number referred to in Article 4, the manufacturer or importer shall generate a product identification number for each product placed on the market.
2. When submitting information on products with the same composition and design, manufacturers and importers shall, to the extent possible, use the same identification number, in particular where data are submitted by various members of a group of companies. This shall apply regardless of brand, subtype and the number of markets on which they are placed.
3. Where the manufacturer or importer is not able to ensure that the same identification number is used for products with the same composition and design, it shall at least provide, in so far as possible the different identification numbers that were assigned to such products.

Article 6

Confidential data and disclosure of data

1. In their submission, manufacturers and importers shall mark all information which they consider to be a trade secret or otherwise confidential and shall duly justify their claims.
2. In using the data transmitted for applying Directive 2014/40/EU and Regulation (EC) No 1049/2001, the Commission shall, in principle, not consider the following information to be confidential or amount to a trade secret:
 - (a) ingredients used in quantities above 0.1% of the final formulation of the liquid;
 - (b) studies on toxicity, addictiveness or attractiveness not linked to specific brands; where those studies are linked to specific brands, the explicit and implicit references allowing to identify the brand shall be removed and the redacted version shall be accessible.

Article 7

Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission

[\[...\]](#)

The President (