This document is an unofficial translation and is provided for information purposes only. The masculine form has been used throughout the text for reasons of readability; nevertheless it refers to both genders.

Rules on reporting obligations about tobacco and related products" (Official Gazette of the RS, No. 9/18) (Official title: Pravilnik o poročanju o tobačnih in povezanih izdelkih (Uradni list RS, št. 9/18)

Based on paragraph 5 of Article 8, paragraph 11 of Article 9, paragraph 7 of Article 10, paragraph 4 of Article 12, paragraph 3 of Article 25, paragraph 14 of Article 26 and paragraph 3 of Article 28 of the Restriction on the Use of Tobacco and Related Products Act (ZOUTPI, Official Gazette of the RS, Nos. 9/17 and 29/17), the ministry of health issues the following

R U L E S

on reporting obligations about tobacco and related products

Article 1
(subject matter)

These rules define:

– the costs of verification of emissions listed in Article 8 of the Restriction on the Use of Tobacco and Related Products Act (Zakon o omejevanju uporabe tobačnih in povezanih izdelkov, Official Gazette of the RS, Nos. 9/17 and 29/17; hereinafter the Act),

– a common format for the submission and making available the information on tobacco products and their sales volume in accordance with the Commission implementing decision (EU) 2015/2186 of 25 November 2015 on establishing a format for the submission and making available of information on tobacco products (OJ L 312 of 27 November 2015, p. 5; hereinafter Decision 2015/2186/EU),

– the fees for receiving, storing, handling, analysing and publishing the data from Article 9 of the Act,

– the priority list of additives used in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations in accordance with the Commission implementing decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations (OJ L 131 of 20 May 2016, p. 88; hereinafter Decision 2016/787/EU),

– the fees for assessments from Article 12 of the Act,

– a common format for reporting on electronic cigarettes and refill containers in accordance with the Commission implementing decision (EU) 2015/2183 of 24 November 2015 on establishing a common format for the notification of electronic cigarettes and refill containers (OJ L 309 of 26 November 2015, p. 15; hereinafter Decision 2015/2183/EU),

– the format for the notification of new tobacco products from Article 25 of the Act,

– the fees for receiving, handling, analysing and publishing the data from Article 26 of the Act,

– the format for reporting on the ingredients of herbal products for smoking from Article 28 of the Act and

–the technical standards for the refill mechanism of electronic cigarettes in accordance with the Commission implementing decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes (OJ L 101 of 16 April 2016, p. 15; hereinafter Decision 2016/586/EU).

Article 2
(the purpose of reporting)

The purpose of reporting obligations concerning tobacco products, electronic cigarettes and refill containers is to ensure a high level of protection in the field of health, protection of the environment and consumer protection.

Article 3
(reporting period)

(1) In accordance with Article 9 of the Act, the manufacturers and importers of tobacco products shall officially notify the National Laboratory of Health, Environment and Food (hereinafter: NLZOH) about each brand and type of tobacco product intend to be placed on the market 30 days before the intended placing on the market.

(2) The manufacturers and importers shall submit to the NLZOH the data from the paragraph 9 of Article 9 of the Act once per year, by 30 April at the latest for the previous year. The data on the sales volume for each brand and type of tobacco product shall be submitted in the format provided in Annex 1, which is an integral part of these Rules.

(3) In accordance with paragraphs 1 and 2 of Article 26 of the Act, the manufacturers and importers of electronic cigarettes and refill containers shall officially notify the NLZOH about any such products intend to be placed on the market 6 months before the intended placing on the market.

(4) The manufacturers and importers of electronic cigarettes and refill containers shall submit to the NLZOH the data from paragraph 6 of Article 26 of the Act once per year, by 30 April at the latest for the previous year. The data from the first indent of paragraph 6 of Article 26 of the Act shall be submitted in the format provided in Annex 1 to these Rules.

Article 4
(reporting format)

(1) The manufacturer or importer of tobacco products shall submit to the NLZOH data on ingredients, emissions and sale volumes of such products, any changes to the submitted data and data on the withdrawal from the market in accordance with the format provided in Article 2 and the Annex of Decision 2015/2186/EU.

(2) The manufacturer or importer of electronic cigarettes and refill containers shall submit to the NLZOH data on the ingredients and emissions of such products, any changes to the submitted data and data on the withdrawal from the market in accordance with the format provided in the Article 2 and the Annex of Decision 2015/2183/EU.

(3) The manufacturer or importer of tobacco products, electronic cigarettes and refill containers shall submit the data from paragraphs 1 and 2 of this Article by means of a common electronic entry gate for data submission operated by the European Commission (hereinafter the Operator).

Article 5
(data storage)

A data storage service offered by the Operator will be used for storage and access to the submitted data in electronic format, in accordance with the signed service level agreement.

Article 6
(identification number of the data submitter)

The manufacturer or importer intending to submit data by means of the common electronic entry gate shall apply for a submitter identification number before the first submission of data in accordance with Article 4 of Decision 2015/2186/EU or Article 4 of Decision 2015/2183/EU.

Article 7
(identification number of the product)

(1) In accordance with Article 5 of Decision 2015/2186/EU or Article 5 of Decision 2015/2183/EU, the manufacturer or importer shall assign a tobacco product identification number (TP-ID) or an electronic cigarette identification number (EC-ID) based on the submitter identification number from the above article to each product to be reported.

(2) The tobacco product or electronic cigarette ID is the basis for charging the fees specified in Article 10 of the present Rules.

Article 8
(trade secrets and confidential data)

In accordance with Article 6 of Decision 2015/2186/EU or Article 6 of Decision 2015/2183/EU, manufacturers and importers shall mark in their submission any data that they consider to be a trade secret or otherwise confidential.

Article 9
(costs of emission measurement verification)

(1) The NLZOH shall charge the manufacturers and importers the costs of the verification of tar, nicotine and carbon monoxide emission measurements in accordance with the applicable price list.

(2) In case of a cigarette containing more than 10 mg of tar, 1 mg of nicotine or 10 mg of carbon monoxide, the NLZOH shall send a written notification to the Health Inspectorate of the Republic of Slovenia.

Article 10
(fees)

(1) The NLZOH shall charge the manufacturers and importers of tobacco products, electronic cigarettes and refill containers a fee of EUR 864.00 for the services from paragraph 10 of Article 9 and paragraph 13 of Article 26 of the Act.

(2) The NLZOH shall charge the manufacturers and importers of tobacco products, electronic cigarettes and refill containers a fee of EUR 250.00 for the services from paragraph 9 of Article 9 and paragraph 6 of Article 26 of the Act.

(3) The NLZOH shall charge the manufacturers and importers of tobacco products a fee of EUR 1,864.00 for the assessment from Article 12, paragraph 4 of the Act.

(4) After the submission of data from paragraphs 1, 2 and 3 of this article, the NLZOH issues the manufacturers and importers a claim for payment of fees. The fee is payable within 15 days from the invoicing date at the latest. In case of late payment, default interests shall be charged in accordance with the applicable regulation of statutory default interest rates.

Article 11
(priority list of additives)

The priority list of additives in cigarettes and roll-your-own tobacco is provided in Decision 2016/787/EU.

Article 12
(reporting of ingredients of herbal products for smoking)

(1) Manufacturers and importers of herbal products for smoking shall submit to the NLZOH a list of all the ingredients and their amounts used in manufacturing each product, separately for each brand and type, in accordance with Annex 2, which is an integral part of these Rules, six months before the intended placing of a new or changed herbal smoking product on the market.

(2) In the submission of the data from the previous paragraph, the manufacturers and importers shall mark all the data from Annex 2 to these Rules, which they consider to be a trade secret or otherwise confidential. The ingredients of a herbal smoking product cannot be considered a trade secret or confidential data.

Article 13
(notification about novel tobacco products)

(1) The manufacturers and importers of novel tobacco products shall notify the NLZOH about each novel tobacco product planned to be placed on the market in accordance with Annex 3, which is an integral part of these Rules, six months before the intended placing of a novel product on the market.

(2) The manufacturers and importers shall attach all the data determined in paragraph 1 of Article 25 of the Act to the official notification from the previous paragraph.

(3) In their submission of the data from paragraphs 1 and 2 of this article in accordance with the provision of paragraph 2 of Article 6 of Decision 2015/2186/EU, the manufacturers and importers shall mark all data from Annex 3 to these Rules that they consider to be a trade secret or otherwise confidential.

Article 14
(refill mechanisms of electronic cigarettes)

Refillable electronic cigarettes and refill containers can only be placed on the market if their refilling mechanism meets the conditions in Article 2 of Decision 2016/586/EU.

TRANSITIONAL AND FINAL PROVISIONS

Article 15
(first reporting period)

The first reporting period in which the manufacturers and importers of tobacco products must prepare a report in accordance with the present Rules ends on 30 April 2018 for the year 2017.

Article 16
(entry into force)

These Rules enter into force the day after publication in the Official Gazette of the Republic of Slovenia.

No. 0070-53/2017
Ljubljana, 31 January 2018
EVA 2017-2711-0011

Milojka Kolar Celarc
Minister of health

Annex 1

Prescribed format for the submission of data on the volume of sales

Type of product	Submitter identification number	Identification number of the product	Product brand	Annual sales volume data*
Cigarettes				
Roll-your-own tobacco				
Cigars				
Cigarillos				
Chewing tobacco				
Nasal tobacco				
Pipe tobacco				
Waterpipe tobacco				
Electronic cigarettes and refill containers				

*If the data has already been submitted in accordance with paragraph 1 of Article 4 of these Rules, only the second (Submitter identification number) and third (Identification number of the product) column of the table must be filled in.

Annex 2

Prescribed format for the submission and making available the data on herbal products for smoking

Brand and type of product	Product ingredients	Amount of the ingredient in the product (mark if the information is considered a trade secret)

Annex 3

Prescribed format for the submission and making available the data on novel tobacco products

Brand and type of novel tobacco product	List of all ingredients and quantities thereof used in the manufacture of the novel tobacco product in descending order of the weight of each ingredient included in the product (mark if the information is considered a trade secret)	Information on tar, nicotine and carbon monoxide emission measurements of the product	Information on other emission measurements of the product	Information on the approval or refusal of the new tobacco product by any of the EU members (state which country issued the approval or refusal)