Pursuant to Articles 8(5), 9(11), 10(7), 25(4), 26(14) and 28(4) and for the enforcement of Article 12(4) of the Restriction on the Use of Tobacco Products and Related Products Act (Official Gazette of the Republic of Slovenia, Nos 9/17, 29/17 and 31/24), the Minister for Health hereby issues the following

RULES

on reporting of tobacco and related products and flavourings in electronic cigarettes and refill containers

Article 1
(Content)

These Rules lay down:

1. the costs of verification of emissions referred to in Article 8 of the Restriction on the Use of Tobacco Products and Related Products Act (Official Gazette of the Republic of Slovenia, Nos 9/17, 29/17 and 31/24) (hereinafter: the Act);
2. a common format for reporting and making available of information on tobacco products and their sales volume in accordance with Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products (OJ L 312, 27. 11. 2015, p. 5) (hereinafter: Decision 2015/2186/EU);
3. the fee for receiving, storing, processing, analysing and publishing the data referred to in Article 9 of the Act;
4. the priority list of additives used in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations in accordance with 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, 20. 5. 2016, p. 88) (hereinafter: Decision 2016/787/EU);
5. the fee for assessments referred to in Article 12 of the Act;
6. a common format for reporting of electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers in accordance with Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ L 309, 26. 11. 2015, p. 15) (hereinafter: Decision 2015/2183/EU);
7. the format for the notification of novel tobacco products referred to in Article 25 of the Act;
8. the fee for receiving, storing, processing and analysing the data referred to in Article 25 of the Act;
9. the fee for receiving, processing, analysing and publishing the data referred to in Article 26 of the Act;
10. the format for reporting of ingredients of herbal products for smoking and herbal heating products referred to in Article 28 of the Act;
11. the fee for receiving, storing, processing, analysing and publishing the data referred to in Article 28 of the Act;
12. the technical standards for the refill mechanism of electronic cigarettes in accordance with Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes (OJ L 101, 16. 4. 2016, p. 15) (hereinafter: Decision 2016/586/EU); and
13. flavourings or substances permitted in electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers.

Article 2
(Purpose of reporting and submission of data)

(1) The purpose of reporting on tobacco products, electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers, novel tobacco products, herbal products for smoking and herbal heating products is to ensure a high level of protection in the field of health protection, environmental protection and consumer protection.

(2) The manufacturer or importer of products regulated by law shall submit the required data to the common electronic data submission portal (hereinafter: common electronic portal) managed by the European Commission (hereinafter: operator).

Article 3
(Reporting period)

(1) In accordance with Article 9 of the Act, 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 intended to be placed on the market 30 days before the intended placing on the market by submitting data to the common electronic portal, in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2186/EU.

(2) Manufacturers and importers shall submit data referred to in Article 9 of the Act to the NLZOH once a year, no later than 30 April for the previous year. Data on the sales volume for each brand and type of tobacco product shall be submitted by entering the data in the common electronic portal in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2186/EU.

(3) In accordance with Article 26(1) and (2) of the Act, manufacturers and importers of electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers shall officially notify the NLZOH about any such products, which they intend to place on the market, by submitting the data to the common electronic portal in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2183/EU 6 months prior to their intended placing on the market.

(4) Manufacturers and importers of electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers shall submit to the NLZOH the data referred to in Article 26(6) of the Act once a year, no later than 30 April for the previous year. The data referred to in the first indent of Article 26(6) of the Act shall be submitted by entering the data in the common electronic portal in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2183/EU.

(5) In accordance with Article 25(1) and (2) of the Act, manufacturers and importers of novel tobacco products shall officially notify the NLZOH about any such products, which they intend to place on the market, by submitting the data to the common electronic portal in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2186/EU 6 months prior to their intended placing on the market.

(6) In accordance with Article 28(1) of the Act, manufacturers and importers of herbal products for smoking and herbal heating products shall officially notify the NLZOH about any such products, which they intend to place on the market, by submitting the data to the common electronic portal in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2186/EU 6 months prior to their intended placing on the market.

Article 4
(Reporting method)

(1) The manufacturer or importer of tobacco products, novel tobacco products, herbal products for smoking and herbal heating products shall submit to the NLZOH data on the ingredients, emissions and sales volumes of these products, changes to the submitted data and data on withdrawals of products from the market, by entering this data to the common electronic portal, in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2186/EU.

(2) The manufacturer or importer of electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers shall submit to the NLZOH data on the ingredients, emissions of these products, changes to the submitted data and data on withdrawals of products from the market, by entering this data to the common electronic portal, in accordance with the format laid down in Article 2 and the Annex to Decision 2015/2183/EU.

Article 5
(Data storage)

Data storage services offered by the operator shall be used for the purpose of storing and accessing the submitted data in electronic format, in accordance with the signed service level agreement.

Article 6
(Data submitter identification number)

The manufacturer or importer who intends to submit data using the common electronic portal shall, prior to the first submission of data in accordance with Article 4 of Decision 2015/2186/EU or Article 4 of Decision 2015/2183/EU, submit a request for the identification number of the submitter. The request is addressed to the European Commission, which is the operator of the common electronic portal (EU-CEG).

Article 7
(Product identification number)

(1) For each product to be reported, based on the submitter identification number referred to in the preceding Article, the manufacturer or importer shall assign the identification number of the tobacco product, novel tobacco product, herbal product for smoking or herbal heating product (TP-ID) in accordance with Article 5 of Decision 2015/2186/EU, and the identification number of the electronic cigarette, nicotine-free electronic cigarette, refill container or nicotine-free refill container (EC-ID) in accordance with Article 5 of Decision 2015/2183/EU.

(2) The TP-ID or EC-ID identification number shall form the basis for charging the fees referred to in Article 10 of these Rules.

Article 8
(Trade secrets and confidential information)

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

Article 9

(Costs of emission measurement verification)

(1) In order to verify the measurements of tar, nicotine and carbon monoxide emissions from cigarettes, the NLZOH shall charge manufacturers and importers of tobacco products the costs of providing these services, in accordance with the applicable price list.

(2) Where the NLZOH determines that a cigarette contains more than 10 mg tar, 1 mg of nicotine or 10 mg of carbon monoxide, it shall send a written notification to the Health Inspectorate of the Republic of Slovenia.

Article 10
(Fees)

(1) The NLZOH shall charge manufacturers and importers of tobacco products, novel tobacco products, electronic cigarettes, nicotine-free electronic cigarettes, refill containers, nicotine-free refill containers, herbal products for smoking and herbal heating products a fee of EUR 864.00 for the services referred to in Article 9(10), Article 25(3), Article 26(13) and Article 28(3) of the Act.

(2) The NLZOH shall charge manufacturers and importers a fee for the services referred to in Article 9(9) of the Act based on the reported quantity of units sold for each TP-ID, as follows:

- 1-100 units = EUR 30.00/TP-ID,
- 101-1000 units = EUR 100.00/TP-ID,
- >1000 units = EUR 300.00/TP-ID.

(3) The NLZOH shall charge manufacturers and importers a fee for the services referred to in Article 26(6) of the Act in the amount of EUR 300 per EC-ID per reported quantity of units sold for each EC-ID.

(4) The NLZOH shall charge manufacturers and importers of tobacco products a fee in the amount of EUR 1 864 for carrying out the assessment referred to in Article 12(4) of the Act.

(5) After the submission of data referred to in the first, second, third and fourth paragraphs of this Article, the NLZOH shall issue a payment request for the fee to manufacturers and importers. The requested amount shall be settled no later than 30 days after the request is issued. In the event of late payment, default interest shall be charged in accordance with the applicable regulation on the prescribed interest rate of default interest.

(6) The amount of the fees referred to in this Article shall be adjusted once a year to the consumer price index published by the Statistical Office of the Republic of Slovenia.

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

(Refill mechanism of electronic cigarettes)

Refillable electronic cigarettes and refill containers may only be placed on the market if the mechanism by which they are refilled meets the conditions referred to in Article 2 of Decision 2016/586/EU.

Article 13
(Permitted substances)

The following substances are permitted, as flavourings, in the liquid or any other component of electronic cigarettes, nicotine-free electronic cigarettes, refill containers or nicotine-free refill containers:

CAS number	Substance name	Substance name in English
35044-68-9	beta-Damascone	beta-Damascone
23726-91-2	(E)-beta-Damascone	(E)-beta-Damascone
23726-92-3	(Z)-beta-Damascone	(Z)-beta-Damascone
23696-85-7	Damascenone	Damascenone
23726-93-4	(E)-beta-Damascenone	(E)-beta-Damascenone
1125-21-9	Ketoisophorone	Ketoisophorone

4883-60-7	2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone	2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone
536-78-7	3-Ethylpyridine	3-Ethylpyridine
350-03-8	3-Acetylpyridine	3-Acetylpyridine
91-10-1	2,6-Dimethoxyphenol	2,6-Dimethoxyphenol
67-47-0	5-(Hydroxymethyl)-2-furfural	5-(Hydroxymethyl)-2-furfural
591-12-8	alpha-Angelica lactone	Alpha-Angelica lactone
503-74-2	Isovaleric acid	Isovaleric acid
1139-30-6	(-)Caryophyllene oxide	(-)Caryophyllene oxide
3738-00-9	Ambroxide	Ambroxide
564-20-5	(3aR)-(+)-Sclareolide	(3aR)-(+)-Sclareolide

TRANSITIONAL AND FINAL PROVISION

Article 14
(Compliance)

Liquids or any other component of electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers must comply with the provisions of these Rules no later than 12 months after the entry into force of the Act amending and supplementing the Restriction on the Use of Tobacco Products and Related Products Act (Official Gazette of the Republic of Slovenia, No 31/24).

Article 15
(Expiry)

The Rules on reporting of tobacco and related products (Official Gazette of the Republic of Slovenia, No 9/18) shall cease to apply as of the date of entry into force of these Rules.

Article 16
(Entry into force)

These Rules shall enter into force on the first day following their publication in the Official Gazette of the Republic of Slovenia.

No.

Ljubljana, date

EVA 2024-2711-0034

Dr Valentina Prevolnik Rupel
Minister
for Health