**Regulations on Tobacco Product Ingredients and Emissions**

**Excerpts of the law of Georgia on Tobacco Control and Sub-normative acts**

1. **Law of Georgia on Tobacco Control**

**“Article 3. Definitions of the terms used in this law**

The terms used in this Law shall have the following meanings:

a) A tobacco product is any product that contains tobacco or its elements (except for medications containing nicotine), and which is intended to be smoked, chewed, snused or sniffed, including:

a. a) filtered and unfiltered cigarettes;

a. b) papirosa, cigars and cigarillos;

a. c) pipe tobacco, tobacco for hookah;

a. d) rolling tobacco;

a. e) chewing, snus and snuff tobacco;

a. f) electronic cigarettes or other similar nicotine-delivering devices containing materials / cartridges / capsules;

a1 ) tobacco accessories and/or devices for tobacco usage such as: a mouthpiece, a pipe, a hookah, a device for snus tobacco and a device for snuff tobacco, an electronic cigarette or a similar device, a special cigarette lighter, tobacco rolling paper, a tobacco rolling device, a tobacco cutting device, an ashtray, any kind of a cigarette case or any other item that is mainly intended for tobacco use and/or storage , as well as any illustrations of cigarettes, cigarette packs or the above mentioned items or any items depicting them.

b) A cigarette is any kind of scroll or a tube-like body that contains tobacco or its elements, and which is rolled in paper or in a tobacco-free material envisaged by law;

c) Nonsmoking tobacco is a tobacco product which is not intended to be smoked. It is intended to be chewed, snused, or inhaled;

d) Tobacco smoking is inhaling the first-hand smoke or vape resulting from burning or heating tobacco;

e) Tobacco industry means manufacturing, importing, selling, exporting, re-exporting and/or transiting tobacco products;

e1) A cigar bar is a specialized institution which is set up according to the permit issued in compliance with the Law of Georgia on Licenses and Permits, and where it is allowed to smoke a cigar envisaged by “a.b.” Subparagraph of this Article;

 f) A medical warning is a statement that warns of the harmful effects of tobacco smoking. It shall include a relevant image;

g)  Rotation is alternation of medical warning messages;

 h) A tobacco product ingredient is tobacco, an additive, or any substance or element contained in a tobacco product, among them, paper, filter, a capsule, ink and glue [Translator: tar can be used instead of glue];

h1) Additive is a substance or material (except a tobacco leaf) which is added to tobacco products;

i) Ministry – the Ministry of Labor, Health and Social Affairs of Georgia;

k) Tobacco product emissions are substances that are released when the tobacco product is used as intended. Namely, the substance contained in the smoke of a cigarette or in that of other kinds of smoking tobacco which is released when the smoking tobacco is used, as well as the substance released when using chewing tobacco, snus tobacco, and snuff tobacco;

k) (deleted on 05.17.2017, №859); (effective May 1, 2018)]

l) Additional materials and items are: a wrapper that comes into contact with a tobacco product, a pack, and other packaging materials;

m) Sale is to transfer a finished tobacco product to another person through selling or marketing it, in order to receive a commercial benefit;

n) Manipulation means weighing, measuring, branding, sealing, packaging, stacking, and moving;

o) Falsification means incompliance of the components, characteristics, assortment and the origin of tobacco products with the defined requirements, or with the data indicated in the documents enclosed and the data included on the label;

p) (deleted on 05.17.2017, №859);

q) Manufacturing entity is an enterprise, shop or their units and other producing subdivisions and compounds, as well as the machinery used in the tobacco production process;

r) (deleted on 05.17.2017, №859);

s) A finished product is a product that is produced by combining the resources and activities (industrial processing);

t) A tobacco manufacturer is a person or legal entity, which produces tobacco and will be held liable for failing to fulfil the requirements of the Law at every stage of carrying out its activities. In addition, it means a representative or a product importer operating in the territory of Georgia, when a foreign manufacturer does not have a representative;

 u) Buildings and other structures are any construction (except a vehicle) which have a floor, any type of roof or ceiling, and at least ½ of their surface (except roofs, ceilings, and floors) has any type of moving or static walls, made of any material, among them open or closed windows and doors;

v) Public transportation is any means of transportation, including, buses, trams, trolley busses, mini-buses, trains, airplanes, subway, ships or other sea vessels, which are used to transfer people and charge fees and/or receive commercial gains.”

**“Article 4. Tobacco Control Activities and Sub-Legislative Normative Acts Governing Tobacco Control**

1. The Government of Georgia shall implement a long-term state strategy and an annual state program of tobacco control.

2. A normative act of the Government of Georgia shall define:

a) The permissible limits of emissions (nicotine, tar, and carbon monoxide gas) from filtered and unfiltered cigarettes intended for sale in Georgia, and the rules and regulations for measurement taking into account the international requirements for tobacco control in effect;

b) The rules of displaying medical warning messages and pictograms on the tobacco product (on a pack/carton, package).

c) The standardization rules for tobacco products intended for sale in Georgia and for their packaging.

3. Measurement of emissions (nicotine, tar and carbon monoxide gas) from filtered and unfiltered cigarettes shall be conducted by a tobacco manufacturer and/or an importer at their own expense. A tobacco manufacturer and/or an importer shall prove that the measurements are carried out in compliance with the measurement standards and shall provide the Ministry with the documents that prove the above before May 31 of every year. The list of the documents to be submitted shall be defined by an order of the Minister of the Ministry of Labor, Health and Social Affairs of Georgia. A tobacco manufacturer and/or an importer shall ensure compliance of the given tobacco product with the data included in the documents. In addition, a tobacco manufacturer and/or an importer shall provide the Ministry with the information on the tobacco product ingredients (namely, the list of ingredients, their quantity and weights) within the time frame defined in this Paragraph.

4. The prohibition/restriction rules, defined by this Law, for manufacturing, importing and selling tobacco shall be reflected in the license/permission/authorization conditions of the entities carrying out the activities defined by a relevant license/permission/authorization.

5. Monitoring compliance with the tobacco control requirements as defined in this Law is the auditing of business activities and thus the Law of Entrepreneurs of Georgia does not apply to it.

6. In the process of preparing, adopting and implementing the decision on tobacco control concerning the protection of health, Government institutions, Government employees and public servants may have communication with entities involved in the tobacco industry only when it is necessary for them to ensure effective regulation of tobacco manufacturing and tobacco products. If communication with entities involved in the tobacco industry is necessary, these Government entities shall conduct communications from the state with entities involved in the tobacco industry in a transparent manner. They shall hold public discussions, and inform the community about such communications through a public notice and disclosure of the documents prepared as a result of such communications. The issues related to such communications shall be defined by a normative act of the Government of Georgia. “

1. **Decree #14 of the Government of Georgia of January 15, 2018 “on the approval of permissible levels, their measurements and regulations as well as health warnings and their appearance on packaging of tobacco products”****Close**

### **Decree No. 14 on the approval of permissible levels, their measurements and regulations as well as health warnings and their appearance on packaging of tobacco products**

 “ **Annex 1.**

**[…]**

**Article 3. Maximum levels, their measurement and regulation rules of the emissions (nicotine, tar, carbon monoxide) of filtered and unfiltered cigarettes to be placed on the market of Georgia**

**1.** The concentration of the emission (tar, nicotine and carbon monoxide) levels from filtered and unfiltered cigarettes to be placed of the market of Georgia shall not be greater than:

**(a)** 10 mg of tar per cigarette;

**(b)** 1 mg of nicotine per cigarette;

**(c)** 10 mg of carbon monoxide per cigarette (only for filtered cigarette).

2. The concentration of the emission (tar, nicotine and carbon monoxide) levels from filtered and unfiltered cigarettes shall be measured according to:

a) ISO standard 4387 for tar,

b) ISO standard 10315 for nicotine,

c) ISO standard 8454 for carbon monoxide.

d) The accuracy of the tar, nicotine and carbon monoxide measurements on the package shall be determined in accordance with ISO standard 8243.

3. Manufacturer and/or importer shall verify the measurement of emission levels (nicotine, tar, carbon monoxide) of filtered and unfiltered cigarettes according to standards and submit to the Ministry of Labor, Health and Social Affairs of Georgia the documents thereon, before May 31 of each reporting year. The list of these documents are approved by the Order of the Minister of Labor, Health and Social Affairs of Georgia. Tobacco manufacturer and/or importer ensures the compliance of the tobacco product with the data indicated in these documents. At the same time, tobacco manufacturer and/or importer shall submit to the Ministry the information on tobacco product ingredients (in particular, the list, quantity and weight of ingredients), within the time-limit indicated in this paragraph.

4. According to Article 12¹.3 of Tobacco Control Law, before January 1, 2019 it is permitted to label the emission levels pursuant to the rules established under this decree on the packs of filtered and unfiltered cigarettes, in accordance with the established results of the measurement ISO standards indicated in paragraph 2 of this Article.”

1. **Order №01-20/N, of May 1, 2018 of the Minister of Labor, Health and Social Affairs of Georgia “on the approval of the list of documents confirming the duly conducted laboratory tests for the emission levels (of nicotine, tar and carbon monoxide) of filtered and unfiltered cigarette and reporting format on ingredients of the tobacco products”**

In accordance with Article 4.3. of the law of Georgia “on Tobacco Control” and subparagraph “m” of Article 5.2 of the decree of the Government of Georgia, of December 31, 2005 “on approving the statute of the Ministry of Labor, Health and Social Affairs of Georgia”,

**I hereby order:**

**Article 1**

The following shall be approved, as annexed:

1. The list of documents confirming the duly conducted laboratory tests for the emission levels (of nicotine, tar and carbon monoxide) of filtered and unfiltered cigarettes (Annex 1).

2. The reporting format on ingredients of the tobacco products (Annex 2).

**Article2**
Tobacco manufacturer and / or importer shall submit the information referred to in Annex 1 and Annex 2 of this order annually until May 31 for the products placed on the market as of the previous reporting year (from April 1 of the previous reporting year to April 1 of the reporting year) to the National Center for Disease Control and Public Health, the LEPL of the Ministry of Labor, Health and Social Affairs of Georgia (hereinafter - Center) in electronic format (USB drive / CD).

**Article 3**

Tobacco manufacturer and/or importer carries out the verification of the measurements referred to in Article 3.1 and 3.2 of the Decree #14 of the Government of Georgia of January 15, 2018 “on the approval of permissible levels, their measurements and regulations as well as health warnings and their appearance on packaging of tobacco products”**Close**

### **Decree No. 14 on the approval of permissible levels, their measurements and regulations as well as health warnings and their appearance on packaging of tobacco products**

 on its expenses, in the authorized laboratories approved by the legislation of Georgia (Article 2 of the Decree #50 07.03.2013 of the Government “on approving the technical regulations of other countries for operational access, the recognition of compliance confirmation documents, the access of specially labeled products in Georgia without conformity assessment procedures, and also, the placement of the products produced in other countries and falling under the regulated areas, in the Georgian market without restrictions ").

**Article 4**

1. The commercial secrets of manufacturer and/or importer at the time of submission of the information referred to in Annex 1 and Annex 2 of this order shall be protected and such reporting obligations shall not put unreasonable burden on manufacturer and/or importer in terms of time, resources and efforts needed for the submission of this information. Tobacco manufacturer and/or importer shall be obliged to ensure the accuracy and the completion of the submitted information. Inaccurate or incomplete submission of information leads to the responsibility of the manufacturer and / or importer according to the procedure established by the legislation of Georgia.

2. Tobacco manufacturer and/or importer shall indicate in the relevant field of the reporting format as approved under Annex 2 of this order, about the confidentiality of the information, which it considers a trade secret.

**Article 5**

The Centre shall not disclose the submitted information referred to in Annex 1 and Annex 2 of this order, and for the purposes of the public health, ensure the due processing and analysis of this information, taking relevant measures for publishing the processed information within its competence and under procedure prescribed by law.

**Article6**

Tobacco manufacturers and/or importers shall be required to refer to the annex template formats (in excel) while filling in the annexes approved by this order, published on the official web-site of the center ([www.ncdc.ge](http://www.ncdc.ge)).

**Annex 7**

This order shall come into force upon its publication.

**Minister of Labor, Health and Social Affairs of Georgia Davit Sergeenko**

**Annex 1**

**The list of documents confirming the duly conducted laboratory tests for the emission levels (of nicotine, tar and carbon monoxide) of filtered and unfiltered cigarettes**

1. The report on the measurement of the concentration of emission levels of filtered and unfiltered cigarettes, in particular nicotine, tar and carbon monoxide thereof, as approved under Article 3.1 and 3.2 of the Decree #14 of the Government of 15 January, 2018.

2. The following documents of the laboratory authorized to conduct the measurement of the concentration of emission levels of filtered and unfiltered cigarettes, in particular nicotine, tar and carbon monoxide thereof, as approved under Article 3.1 and 3.2 of the Decree #14 of the Government of 15 January, 2018:

a) The name (title) and the document (license) confirming the authorization of its activity;

b) The conclusion (certificate) on the conduct of the measurement of emission levels in compliance with the standards.

|  |  |
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| **Annex 2 - The reporting format on ingredients of the tobacco products**  |  |
|  |
| **1. Identification Data of Manufacturer / Importer** |  |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** |  |
| **1** | ID |  |  |  |
| **2** | Name of entity / company (official name of submitter) |  |  |  |
| **3** | Type of Activity (if submitter is manufacturer or importer)  |  |  |  |
| **4** | legal address of entity / company |  |  |  |
| **5** | factual address of entity / company (if different from legal address) |  |  |  |
| **6** | contact details of entity (telephone and email) |  |  |  |
| **7** | person responsible for filling in the reporting forms / head of entity (name, surname) |  |  |  |
| **8** | Contact details of person responsible for filling in the reporting forms / head of entity  |  |  |  |
| **2. Tobacco Product Description** |  |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
| **1** | Tobacco Product type |  |  | indication of type of tobacco product |
| **2** | tobacco product length  |  |  | indication of average length of product unit in mm |
| **3** | tobacco product diameter  |  |  | Average diameter (measured at the point with maximal diameter) of the product unit in mm |
| **4** | tobacco product weight |  |  | Weight of one product unit((One unit for loose tobacco is 1 g.), including the moisture, in mg  |
| **5** | tobacco weight in product |  |  | Total weight of the tobacco in one product unit in mg |
| **6** | identification of tobacco product manufacturer |  |  | If the submitter is not the manufacturer, the official company name(s) of the manufacturer(s) of the product including its contact details |
| **7** | tobacco product filter |  |  | Existence of a filter in the product |
| **8** | tobacco product filter length |  |  | Length of the product filter in mm |
| **9** | tobacco product production site address |  |  | For each manufacturer, address(es) of the site(s) where production is completed |
| **10** | Tobacco product technical file |  |  | Technical document setting out a general description of the additives used and their properties |
| **11** | Tobacco product brand name |  |  | indication of name of tobacco product brand |
| **12** | Tobacco product brand subtype name |  |  | Product ‘subtype name’ (if any) under which the brand is registered in the market |
| **13** | Tobacco product launch date in market |  |  | Date on which the submitter launched the product on the market |
| **14** | Tobacco product withdrawal date |  |  | indicate date of withdrawal if a product was withdrawn during period  |
| **15** | tobacco product internal ID |  |  | ID number used internally by the submitter (if any) |
| **16** | Tobacco product UPC number |  |  | UPC-12 (Universal Product Code) of the product (if any) |
| **17** | tobacco product EAN number |  |  | EAN-13 or EAN-8, (European Article Number) of the product if any |
| **18** | Tobacco product GTIN number |  |  | GTIN (Global Trade Identification Number) of the product, if any |
| **19** | Tobacco product SKU number |  |  | SKU (Stock Keeping Unit) number(s) of the product (if any) |
| **20** | unit number in tobacco product package |  |  | Number of individual product units in the unit packet / box |
| **3. Description of ingredients: Tobacco** |
| *For each of the tobacco ingredients used in the product, the following variables must be completed for each combination of leaf cure method, leaf type and part type.* |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
| **1** | tobacco element type |  |  | Type of tobacco part |
| **2** | tobacco element description |  |  | General description of the manufactured part type in the recipe. The description must provide detailed information on the quantitative and qualitative composition of the manufactured tobacco |
| **3** | tobacco element supplier |  |  | For each supplier, the official company name(s) including its contact details |
| **4** | tobacco leaf type |  |  | Type of tobacco leaf used |
| **5** | tobacco leaf cure method |  |  | Method used to cure the tobacco leaf |
| **6** | tobacco element quantity |  |  | Weight per product unit in mg |
| **4. Description of Ingredients: additives and other substances / elements** |  |
|  | *for each of the tobacco ingredients used in the product, the form must be completed separately.* |  |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
| **1** | Ingredient category |  |  | Category of product component (e.g. filters, papers etc.) |
| **2** | Ingredient name |  |  | Chemical name of the ingredient, if any |
| **3** | Ingredient CAS Number |  |  | CAS (Chemical Abstracts Service) number, if any |
| **4** | Ingredient CAS additional number |  |  | Additional CAS numbers if applicable |
| **5** | Ingredient FEMA number |  |  | FEMA (Flavor and Extract Manufacturers Association) number if any |
| **6** | Ingredient Additive number € |  |  | If the ingredient is a food additive, its food additive ‘E number’, if any |
| **7** | Ingredient FL number |  |  | FL number, if any (European Flavoring number) if any |
| **8** | Ingredient EC number |  |  | European Community (EC) number if any |
| **9** | Ingredient Quantity Fluctuate |  |  | Indication whether the ingredient quantity fluctuates across production batches |
| **10** | Ingredient Recipe Quantity |  |  | Standard weight of the ingredient included in one product unit in mg according to recipe |
| **11** | Ingredient recipe range minimum level |  |  | indication of the lowest weight (in mg) of the ingredient for adjusting tobacco leaf natural variations in one product unit indicated in recipe, if the declared quantity fluctuates /varies |
| **12** | ingredient recipe range maximum level |  |  | indication of the highest weight (in mg) of the ingredient for adjusting tobacco leaf natural variations in one product unit indicated in recipe, if the declared quantity fluctuates /varies |
| **13** | Ingredient Measured SD |  |  | Statistically derived standard deviation of the mean quantity of ingredient added per product unit within each standardized batch |
| **14** | Ingredient function |  |  | Function(s) of the ingredient |
| **15** | Ingredient Priority Additive |  |  | Indication whether the ingredient is part of the priority list (See annexed list of priority additives)  |
| **16** | Ingredient Unburnt Status |  |  | Indication whether the ingredient in unburnt form is characterized by any known type of toxicity or has carcinogenic, mutagenic or toxic for reproduction properties  |
| **17** | Ingredient REACH registration number |  |  | Registration number pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council, if any |
| **18** | Ingredient CLP Classification |  |  | Ingredient classification with regard to Regulation (EC) No 1272/2008  |
| **19** | Ingredient Tox Data |  |  | Availability of toxicological data, concerning a substance, either in isolation or as part of a mixture. In each case, specify whether the toxicological data relate to the substance in burnt or unburnt form |
| **20** | Ingredient Tox CMR in terms of reproduction, carcinogenicity and mutagenicity  |  |  | Existence of any study relating to the carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient (if any) |
| **21** | Ingredient Tox Cardio Pulmonary |  |  | Existence of in vitro and in vivo assays to evaluate the toxicological effects of the ingredient on the heart, blood vessels or respiratory tract (if any) |
| **22** | Ingredient addictiveness |  |  | Indication of information on the possible addictive properties of the ingredient (if any)  |
| **23** | Other toxicological data of ingredient |  |  | Indication of any other toxicological data not stated above (if any) |
| **24** | Ingredient Tox/Addictive File |  |  | Upload documentation on analysis of toxicological/addictiveness data of ingredients indicated in points 19-23 of this form (if any) |
| **5. filtered cigarette specific:** |  |
| *To be filled in additionally only in case of filtered cigarette* |  |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
| **1** | Cigarette Characterizing Flavor |  |  | Classification of the cigarette as having a characterizing flavor |
| **2** | Cigarette Filter Ventilation |  |  | Total ventilation of the filter (0-100 %) |
| **3** | Cigarette Filter Drop Pressure Closed |  |  | Drop of pressure with closed vents (mmH2O) |
| **4** | Cigarette Filter Drop Pressure\_ Open |  |  | Drop of pressure with open vents (mmH2O) |
| **6. Smokeless Tobacco (chewing, oral, nasal ) Specific:** |  |  |
| *To be filled in additionally only in case of smokeless tobacco* |  |  |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
| **1** | Smokeless pH |  |  | pH of the product |
| **2** | Smokeless Nicotine Content |  |  | Total nicotine content of the product per product unit |
| **7. Roll-your-own and Pipe Tobacco Specific:** |  |
| *o be filled in additionally only in case of roll-your-own and pipe tobacco* |
| **№** |  | **information(to be filled by submitter )** | **information confidential(filled by submitter in case this information is confidential )** | **Remark** |
|  | Roll-your-own/pipe Total Nicotine Content |  |  | Total nicotine content of the loose product per product unit (in 1 gr) |
|  |  |  |  |  |
| **\* Priority list of additives** |  |
|  | **Additive** | **Chemical formula (if applicable)**  | **CAS number(s) applicable to the substance (not exhaustive)** |
|  | Carob bean |  | 9000-40-2, 84961-45-5 |  |
|  | Cocoa |  | 84649-99-0, 84649-99-3, 95009-22-6, 8002-31-1 |
|  | Diacetyl | C₄H₆O₂ | 431-03-8 |  |
|  | Fenugreek |  | 68990-15-8, 977018-53-3, 84625-40-1 |
|  | Fig |  | 90028-74-3 |  |
|  | Geraniol | C₁₀H₁₈O | 106-24-1, 8000-46-2 |  |
|  | Glycerol | C₃H₈O₃ | 56-81-5 |  |
|  | Guaiacol  | C₆H₄(OH)(OCH₃) | 90-05-1 |  |
|  | Guar gum |  | 9000-30-0 |  |
|  | Liquorice |  | 68916-91-6 |  |
|  | Maltol | C₆H₆O₃ | 118-71-8 |  |
|  | Menthol | C₁₀H₂₀O  | 2216-51-5, 15356-60-2, 89-78-1, 1490-04-6, 8006-90-4, 68606-97-3, 84696-51-5,8008-79-5 |  |
|  | Propylene glycol | C₃H₈O₂ | 57-55-6 |  |
|  | Sorbitol | C₆H₁₄O₆ | 50-70-4 |  |
|  | Titanium dioxide | TiO₂ | 13463-67-7, 1317-70-0 |  |
|  |  |  |  |  |
|  |  |  |  |  |