### Decree N01-20/N May 1, 2018

### From the Minister of Labor, Health and Social Affairs of Georgia

#### **Tbilisi**

Regarding the list of documents confirming measuring of substances (nicotine, tar, choking gas) emitted from the filtered and unfiltered cigarettes by tobacco manufacturer or/and importer in accordance to the measuring standards and confirmation of information report forms on tobacco product ingredients.

Georgian law, article 4, paragraph 3 "on Tobacco Control" and "confirmation of statute of the Georgian Ministry of Labor, Health and Social Affairs" in accordance to the Georgian government decree N249 dated 31 December, 2005 confirming article 5, paragraph 2, subparagraph "N" of the decree, I declare:

#### Article 1

To confirm the attached:

- 1. The list of documents confirming conducting measuring of substances (nicotine, tar, choking gas) emitted from the filtered and unfiltered cigarettes according to the measuring standards (attachment N1).
- 2. The information report forms regarding tobacco product ingredients (attachment N2).

#### **Article 2**

Tobacco manufacturer or/and importer with N1 and N2 attachments confirmed by this decree will supply certain information from the prior year (from April 1 of last year through April 1 of the fiscal year) regarding tobacco product on the market to the legal entity of public law under the state control of Georgian Ministry of Labor, Health and Social Affairs — National Center of Decease Control and Public Health named after L. Sakvarelidze (later indicated as - Center) with electronic form (disc/information (USB) drive), every year until May 31.

#### Article 3

Tobacco manufacturer or/and importer "norms allowed for substance (nicotine, tar, choking gas) emitted from filtered and unfiltered cigarettes intended for sale in Georgia, their measuring and regulation norms in the areas where tobacco product is sold, as well as medical warning and how it is placed on the box/block and package" in accordance to the decree N14 by the Georgian government dated January 15, 2018 (later indicated as – decree N14 by the Georgian government dated January 15, 2018) article 3, paragraph 2 regulation on measuring the concentration of substances, in particular nicotine, tar and choking gas emitted from filtered and unfiltered cigarettes using its own funds, in accordance to the Georgian legislation in the authorized/accredited laboratories "admitting other countries' technical rules as valid by Georgia, admitting corresponding documents as valid, admitting branding product in Georgia without additional evaluation procedures, as well as to admit placement of the product manufactured in other countries and belonging to the regulatory area on the Georgian market without limitations" in accordance to the article 2 of the decree N50 of the Georgian government dated March 7, 2013.

#### Article 4

- 1. In the Information indicated in attachments N1 and N2 confirmed by this decree, during the reporting period, the commercial secrecy of the tobacco manufacturer or/and importer is protected and such reporting does not impose on the tobacco manufacturers or/and importers undocumented burden in regards to composing this information and necessary time, expenses and effort for reporting. Tobacco manufacturer or/and importer is obligated to guarantee the accuracy of such information and to fully supply it. Supplying information that is inaccurate or not full, will be subject to investigation of the manufacturer or/and importer according to the Georgian legislation.
- 2. While filling out reporting forms in accordance to the attachment N2 of this decree, the tobacco manufacturer or/and the importer indicates the confidentiality of information in the corresponding section, which is a commercial secret.

### **Article 5**

The center is obligated not to disclose the information obtained by attachments N1 and N2 confirmed by this decree, as well as to supply processing and analysis of the above information due to public health and to take corresponding measures in regards to publicly disclosing the above processed information in the framework of competency and the rules set by the legislation.

### **Article 6**

To request from the tobacco manufacturers or/and importers to utilize the samples of the attachments (Excel) format, which is on the official website of the center (www.ncdc.ge) while filling out the attachments confirmed by this decree.

### Article 7

The decree shall be valid upon publishing.

The Minister of Georgian Ministry of Labor, Health And Social Affairs

**Davit Sergeenko** 

Attachment N1

The list of documents confirming conducting of measuring standards of substances (nicotine, tar, choking gas) emitted from the filtered and unfiltered cigarettes

- 1. The regulation confirmed by the Georgian government decree N14, article 3, paragraphs one and 2 dated January 15, 2018 regarding the report on the authorized laboratory measuring substances, in particular nicotine, tar and choking gas concentration emitted from the filtered and unfiltered cigarettes.
- 2. The following information of the authorized laboratory conducting measurement of substances, in particular nicotine, tar and choking gas concentration in accordance to the decree N14, paragraph 3, articles one and 2 of the Georgian government dated January 15, 2018:

- a) Name and the document confirming validity of activity;
- b) Conclusion (report) regarding conducting measurement standards of the emitted substance.

**Attachment N2** 

# Reporting forms regarding information on tobacco product ingredients

# 1. Identification data of the manufacturer or/and importer:

N		Information	The information is confidential
		(the row is filled out by the supplier of the information)	(filled out by the supplier in case of confidentiality of the above information)
1	Identification number		
2	Name of the establishment/company		
	(the official name of the supplier)		
3	Type of activity		
	(is indicated whether the supplier is a manufacturer or importer)		
4	Legal address of the establishment/company		
5	Factual address of the establishment/company		
	(is filled out if the factual address is different from the legal address)		
6	Contact information of the establishment:  Telephone, electronic mail		
7	Responsible person/head of the establishment (first		

	and last name) for filling	
	the forms out	
8	Contact information of the responsible person/establishment for filling out the reporting forms	

# 2. Name of the tobacco product:

N		Information	Information is confidential	Remark
		(the row is filled up		
		by the report	(filled out by the	
		supplier)	supplier in case of	
			the confidentiality	
			of the above	
			information)	
1	Type of the tobacco			Tobacco product
	product			type is indicated
2	Length of the			The average
	tobacco product			length of the unit
				of the product is
				indicated in
				millimeters
3	Tobacco product			The unit of the
	diameter			product diameter
				(the measurement
				point of maximum
				diameter) in
				millimeters
4	Tobacco product			The weight of the
	weight			unit of the product
				is indicated (one
				unit of the
				wrapping tobacco
				is 1 gram)
				including
				humidifier (in
				milligrams)
5	Tobacco weight in			The total weight of
	the product			the unit of the
				product is

		indicated in
		milligrams)
6	Identification of	If the presenter is
	tobacco product	not a
	manufacturer	manufacturer,
		indicate the
		official name(s) of
		product
		manufacturer(s),
		including the
		contact
		information
7	Tobacco product	The presence of
	filter	filter in the
		product is
		indicated
8	Length of the	The length of the
	tobacco product	filter is indicated
		in millimeters
9	Address of the	Product
	manufacturing place	manufacturing
	of the tobacco	country/address is
	product	indicated for each
	•	manufacturer
10	Technical document	Technical
	of the tobacco	document used to
	product	describe general
	1	description of
		additives and
		about their
		property
11	Name of the	The product brand
	tobacco product	name is indicated
	brand	is indicated
12	Name of the	The name of the
	tobacco product	brand subtype, if it
	brand subtype	exists, according
	Statia Sastype	to which the
		product is
		registered on the
		market
<u></u>		Illarket

### 3. Description of ingredients: tobacco

The form is filled out when each leaf is processed and for each combination of the leaf type and element type for each tobacco ingredient used in the product.

N	Area	(the field is filled out by the supplier of the report)	Information is confidential  (is filled out by the presenter in case of the confidentiality of the above information)	Remarks
1	Type of the tobacco element			The tobacco element type is indicated
2	Description of the tobacco element			The general description in the recipe of the manufactured element is indicated. The description should include detailed information on the number and quality ingredients of the manufactured tobacco
3	Supplier of the tobacco element			The information on each supplier is indicated, indicate the official name of the company including the contact information
4	Type of the tobacco leaf			The type of tobacco leaf used is indicated
5	The method of tobacco leaf processing			The method, which is used for processing the tobacco leaf is indicated
6	The number of tobacco elements			The weight in milligrams for each unit of the product is indicated

## 4. Description of the ingredients: additives and substance/elements

The form is filled out for each ingredient separately

N		(the field is filled out by the supplier of the report)	Information is confidential  (is filled out by the supplier if the information is confidential)	Remarks
1	The category of the ingredient		,	The category of the product ingredient is indicated (filter, paper, etc.)
2	The name of the ingredient			The chemical name of the ingredient is indicated if such exists
3	CAS (registration number of the chemical substance) number of the ingredient			The CAS number is indicated if such exists
4	The additional CAS (registration number of the chemical ingredients) number of the ingredient			The additional CAS number is indicated, if such exists
5	FEMA (the association of aromatics and extracts manufacturer) number of the ingredient			The FEMA (the association of aromatics and extracts manufacturer) number is indicated, if such exists
6	The ingredient additive number (E)			If the ingredient is a food additive, the E number of the food additive is indicated, if such exists
7	The FL (European aromatizer) number of the ingredient			The FL number (European aromatizer) is indicated if such exists

8	The EC (European	The European Union
	Union) number of the	number is indicated if
	ingredient	such exists
9	The change in the	The information is
	ingredient amount	indicated whether
	ingreatene amount	the number of
		ingredients is in the
		product series
10	The amount of	The standard weight
10	ingredients indicated in	of the ingredients in
	the recipe	the product unit is
	thereape	indicated in
		milligrams, according
		to the recipe
11	The minimal level of	In order to specify
	ranging the ingredients	the natural variations
	indicated in the recipe	of the tobacco leaf in
	indicated in the recipe	the unit product
		indicated in the
		recipe, the lowest
		weight of the
		ingredient (in
		milligrams) if the
		declared amount
		changes/varies
12	The maximum level of	Is indicated in order
12	the range of the	to specify the highest
	ingredients indicated in	weight (in milligrams)
	the recipe	of the ingredient in
	thereupe	the unit product in
		order to specify the
		natural variations of
		the tobacco leaf if
		the declared amount
		changes/varies
13	The standard deviation	Indicated in each
13	(SD) of the measured	standardized series
	ingredient	ingredient's average
	bicalciit	weight added to the
		unit product, which is
		calculated according
		to the average
		statistics
		Statistics

14	The function of the	The ingred	ient's
1-	ingredient	function/fu	
	iligieuleilt	are indicat	
15	The priority of the	Indicative	.eu
13	ingredient's additive	informatio	n on
	ingredient's additive		
		whether th	
			is the part
		of establish	
		prioritized	•
		the attache	
		for the price	ority
		additives)	
16	The status of non-		nformation
	inflammatory ingredient	on whethe	
		ingredient	
		while in th	
		inflammat	
		or whethe	
		carcinoger	*
		mutagenic	
		reproducti	
		properties	
17	Ingredient's registration	The number	
	REACH (registration,	indicated i	
	evaluation,	exists (acco	_
	authorization and	the Regula	
	limiting of chemical	No 1907/2	.006 if such
	substance) number	exists)	
18	The ingredient CLP (with	The ingred	ient's
	marking and packaging	classification	on is
	classification)	indicated (	according
		to the regu	ulation (EC)
		No 1272/2	.008, I such
		exists)	
19	Information regarding	The inform	nation is
	the toxicity of the	indicated r	egarding
	ingredient	the toxicity	y of the
		substance	despite
		the fact wh	nether it is
		isolated or	part of
		the compo	ound, in
		each case	indicate
		the toxicity	y during

			burning or in the
			non-inflammatory
			stage (if such exists)
20	Ingredient's toxicity		The information is
	during CMR		indicated regarding
	reproduction in terms		the study confirming
	of carcinogenicity and		the ingredient's
	mutation		reproduction
			carcinogenicity,
			mutagenicity or
			toxicity (if such
			exists)
21	Ingredient's toxicity in		The information is
	regards to		indicated regarding
	cardiopulmonary		in-vitro and in-vivo
	system		studies. Regarding
			the impact of the
			ingredient's toxicity
			on the heart and
			vascular system and
			breathing organs (if
			such exists)
22	Ingredient's addictivity		The information is
			indicated regarding
			the ingredient which
			causes dependence
			(if such exists)
23	Other indicator of the		The information is
	ingredient's toxicity		indicated on the
			ingredient's other
			toxic qualities, which
			is not indicated in the
			above table
24	The documentation		Attach the
	confirming the		documents to the
	ingredient's		report regarding the
	toxicity/addictivity		study confirming the
			ingredients'
			toxic/addictive
			properties indicated
			in the 19-23
			paragraphs (if such
			exists)

## 5. Type of filtered cigarette:

The form is filled out in addition in case of the filtered cigarettes only

N		Information  (the box is filled out by the report supplier)	Information is confidential  (is filled out by the supplier in case the above information is confidential)	Remark
1	Aroma depicting cigarettes			Description/classification of the cigarette aroma, if such exists
2	Cigarette filter ventilation			The information is indicated on the filter's full ventilation (0-100%)
3	The cigarette filter's unvented filter			The level of impact is indicated with unvented filter (mmH2O)
4	Cigarette filter's vented filter			The level of impact is indicated with vented filter (mmH2O)

# 6. Non-smoking tobacco – chewing tobacco, dip tobacco, sniffing tobacco types:

The form is filled out additionally only in case of non-smoking tobacco

N		Information (the box is filled out by the report submitter)	The information is confidential  (filled out by the submitter in case the information is confidential)	Remark
1	Non-smoking tobacco's pH			The product's pH is indicated
2	The content of nicotine in a non-smoking tobacco			The total amount of nicotine in the unit product is indicated

# 7. The type of wrapping tobacco and pipe tobacco:

The form is filled out additionally only in case of wrapping tobacco and pipe tobacco

N		Information (the box is filled out by the report submitter)	The information is confidential  (filled out by the submitter if the	Remark
			information is confidential)	
	The full nicotine amount in the wrapping tobacco/pipe tobacco		,	The full amount of nicotine is indicated in the product's raw material (1 gram)

# • Priority list of the additives

Additive	Chemical Formula	CAS number (numbers) given to the substance
	(if it exists)	
Locust seed		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 extract		90028-74-3
Geraniol	C10H18O	106-24-1, 8000-46-2
Glycerin	C3H8O3	56-91-5
Guaiacol	C6H4(OH)(OCH3)	90-05-1
Guar gum resin		9000-30-0
Bot liquorice		68916-91-6
extract		
Maltose	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