Bogotá D.C

SUPERINTENDENCY OF INDUSTRY AND

COMMERCE

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3100 INVESTIGATION FOR THE PROTECTION **EVE: 328 COMPLAINT**

DIRECTION OF

PROC: 187

TRA: 187 PROTECONSU

ACT: 330 COMUNICACIDN

Sir

NICOLAS PARRA CASTRO

juridica2@educarconsumidores.org BOGOTÁ D.C. – COLOMBIA

Subject: Filing: 17-82520- -58-0

> Proceeding: 187 Event: 328 Issue: 330 Pages: 16

Respected Sir:

It is the faculty of the Superintendency of Industry and Commerce, based on the powers of inspection, surveillance and control granted by the Decree 4886 of 2011, to verify, among others, the compliance of the rulings relating to the suitability, quality, minimum information, public price information, advertising, promotions, product safety, general conditions and adhesion contracts, operations through financing systems, sales using nontraditional methods or through distance, and electronic commerce of goods and services set forth in the Statute of the Consumer -Law 1480 of 2011- and the decrees that regulate it.

In exercise of the aforementioned functions, the Directorate of Investigations of Consumer Protection, was informed of the complaint brought by Mr. JAIME HERNAN ARCILA SIERRA, filed under No. 17-082520 of April 4, 2017, by the following facts:

"(..)

- 1. On March 22, 2017, the Director of La Luciernaga of Caracol Radio announced in the second part of the program that Phillip Morris is launching this weekend, on the Estéreo Picnic Festival, its famous IQOS.
- 2. IN AN INTERVIEW WITH DATAIFX, Humberto Mora, vice president of Coltabaco, stated that this product that they are launching is an electronic device that heats tobacco units called HEETS at controlled temperatures which are well below the levels of combustion. By heating the tobacco, instead of burning it, IQOS does not produce smoke; the device generates vapor, without generating ashes and with less odor than conventional cigarettes, thus without negatively affecting indoor air quality.

Mora emphasized that IQOS is a very different product from conventional cigarettes, in the sense that they do not burn. He added that it is not an electronic

cigarette because it contains tobacco; it contains tobacco that is consumed by heating.

(..)

On March 23, 24 and 25, 2017, the Estéreo Picnic festival 2017 was held, in which the line of products under the names IOQS and HEETS was widely promoted.

In Colombia, the web page http://www.iqos.com.co is active, where, in addition to the promotional mentions of the product and brands, an IQOS user guide is available, where one can read that IQOS works exclusively with Philip Morris International's HEETS MARLBORO warming tobacco.

The Rappi Colombia app promotes the sale and/or consumption of IQOS and HEETS products.

(...)"

Regarding the complaint described, and in order to carry out the corresponding preliminary investigation, this Directorate, through files No. 17-82520-4 and 17-82520-5 of June 16, 2017, required to COMPAÑIA COLOMBIANA DE TABACO SAS, COLTABACO SAS, the following:

- 1. To describe each product and its presentations on the market.
- 2. To attach the technical data sheet of the products.
- 3. To indicate whether under the name of these products any event has been sponsored in Colombia, and in case of an affirmative answer, to indicate which events and to provide the advertising pieces and other documents related to them.
- 4. To list all the advertising pieces with which the products were offered and/or offered, indicating the broadcasting networks and the frequency with which they are broadcasted.
- 5. To inform from which date and through which channels the products are marketed.
- 6. To attach an importation certificate issued by DIAN regarding the products.
- 7. To provide a copy of the authorization issued by the Ministry of Social Protection for the labeling of the products.
- 8. To attach a copy of each pack of products."

That in addition to the above, this Directorate addressed the company PHILIP MORRIS COLOMBIA SA through files No. 17-82520-6 and 17-82520-7 of June 16, 2017, in order to indicate the following:

• To inform whether the products called IQOS and HEETS are sold in Colombia, hereinafter referred as "the products", and if so:

"(...)

- 1. To describe each product and its presentations on the market.
- 2. To attach the technical data sheet of the products.
- 3. To indicate if under the name of these products any event has been sponsored in Colombia, and in case of an affirmative answer, to indicate which events and to provide the advertising pieces and other documents related to them.
- 4. To list all the advertising pieces with which the products were offered and/or offered, indicating the broadcasting networks and the frequency with which they are broadcasted.
- 5. To inform from which date and through which channels the products are marketed.
- 6. To attach an importation certificate issued by DIAN regarding the products.
- 7. To provide a copy of the authorization issued by the Ministry of Social Protection for the labeling of the products.
- 8. To attach a copy of each pack of the products."

That through file No. 17-082520-11 of July 04, 2017, COLTABACO SAS answered the requirement formulated by this Directorate, highlighting that:

"(...)

IQOS is an electronic heating device that, when used with the consumable tobacco units identified with the distinctive HEETS sign, emit an aerosol that can be inhaled.

Indeed, the use of the IQOS heating system does not light the tobacco, since it does not generate or create combustion and therefore does not generate tobacco smoke. Thus, instead of generating combustion to ignite the tobacco and produce smoke, what IQOS does is to heat the special consumable tobacco units (HEETS), to produce an aerosol that contains significantly lower levels of harmful components compared to those contained in cigarette smoke. Consequently, as proved by clinical and toxicology studies, the aerosol generated by these products contains between 90% and 95% less toxic components compared to the smoke generated by tobacco combustion and has great potential to reduce the risks of harm to adult smokers who switch to them, instead of continuing smoking cigarettes.

IQOS includes two main components: (i) an electronic heating device, and (ii) an electronic charger for the device's battery. The device, the technical description of the heating system and its instructions for use, which describe and illustrate its operation (...)

HEETS constitutes a category of tobacco products entirely new on the market, which is called HEAT- WITHOUT- BURN.

(...)

The HEETS are inserted into the IQOS device, which heats the tobacco from the consumable unit to generate an inhalable aerosol that is not smoke. Because of this, HEETS are materially different from cigarettes and are not smoked either, like cigarettes are.

(...)

Consequently, since HEETS are not used to be smoked, because the IQOS system prevents combustion, ignition and smoke, the HEETS do not belong to the category of cigarettes and IQOS is an electronic device.

(...)

No event has been sponsored in Colombia under the name IQOS or HEETS. Given that the complaint with which this preliminary inquiry arises seems to refer to the Estéreo Picnic 2017 Festival as an event sponsored by IQOS or HEETS, in the Annex #5 I allow myself to provide an impression of the festival's website, in which at the bottom the sponsoring brands of said event can be seen, without any of them corresponding to IQOS or HEETS. Coltabaco was present at the Estéro Picnic 2017 Festival to sell their IQOS and HEETS products, but there was no sponsorship.

The advertising of IQOS consists of a balloon showing the IQOS brand, dummies or scale models of the IQOS device and material displayed at exhibition points or stands with the IQOS sign.

(...)

As mentioned in this memorial, IQOS is an electronic device, so it is not subject to authorization by the Ministry of Health and Social Protection.

(...) although HEETS contain tobacco, it does not light, does not generate combustion and does not generate smoke, for that reason HEETS, (...) are not smoked, because they do not generate smoke, but an aerosol (...)

Thus, since HEETS are not smoked, because there is no combustion, they do not light and they do not produce smoke, the pictograms and warning phrases issued by the Ministry of Health for cigarettes are not applicable to them because they do not reflect the characteristics of the product.

In the absence of warnings created for non-combustible products, we put the image with the legend "Your future lungs" in the HEETS because it is the only legend issued by the Ministry of Health that does not refer to smoking.

That COLTABACO S.A.S provided the following documentation:

- 1. Certificate of the legal constitution and representation of COLTABACO SAS.
- 2. IQOS device, technical description of the heating system and its instructions for use.

- 3. HEETS product packaging presentations
- 4. HEETS Product Data Sheet
- 5. Printing of the Estéreo Picnic 2017 Festival website showing the sponsoring brands of said event.
- 6. Photo of the globe with the IQOS brand and photos of the dummies or scale models of the IQOS device.
- 7. Copy of the import certificates of HEETS and IQOS issued by the DIAN.
- 8. Resolution 2463 of April 4, 2016, of the DIAN.
- 9. Communications sent by COLTABACO to the Ministry of Health requesting the issuance of health warnings for tobacco products and their derivatives that are consumed without combustion.

That for its part, the PHILIP MORRIS COLOMBIA S.A company responded to the request of information by official letter No. 17-082520-12 of July 4, 2017, indicating the following:

"Faced with the requested information, I allow myself to state that the Philip Morris Colombia SA society, does not produce, import or commercialize the products IQOS and HEETS in the Colombian market."

That the legal representative of COLTABACO SAS provided additional information to the request, through official letter No. 17-82520-13 of July 21, 2017, in the following terms:

(...)

In section 6, when the text of Resolution 2463 of the DIAN, of April 4, 20J'6, is cited, according to which HEETS are tobacco products that do not light, is not smoked and do not require combustion, the product to be classified cannot be considered a cigarette, of those included in tariff nomenclature 24.02. That according to the above, it is concluded that, by its tariff, the merchandise corresponds to a reconstituted tobacco product, which also contains binding and moistening substances, included in nomenclature 24.03 of the tariff harmonized system nomenclature.

In section 7.b when we affirm that, as it has been pointed out repeatedly, although the HEETS contain tobacco, it does not ignite, does not generate combustion and does not generate smoke (...).

That this Directorate gave a scope to the request for information filed with numbers No. 17-82520-4 and 17-82520-5 of June 16, 2017, through official letter No. 17-82520-15 of October 5, 2017, by virtue of which it was requested to COLTABACO SAS to attach a sample of the product called HEETS, which was provided by this company through official letter No. 17-082520-16 of October 24, 2017.

That successively, the Director of Promotion and Prevention of the Ministry of Health and Social Protection carried out the transfer of the petition presented to them by Mr. JAIME HERNAN ARCILA SIERRA, which was registered in this Agency through the file No. 17-082520-17 of January 31, 2018 (fls. 193 to 201).

That in addition to the above, this Directorate knew of the complaint filed under No. 17-401823 of December 1, 2017, presented by Mr. JAIME HERNAN ARCILA SIERRA, which is based on the following facts:

"(...)

Last November 15, it was published on the Canal Caracol website the following information:

In November, Bogota officially welcomes Christmas with Santa Market.

With the arrival of Santa Market to Bogota, the official opening to the most beautiful and long-awaited season of the year will take place.
(...)

As shown in the media article, this is a Christmas event, with a family call, with the presence of symbols that are clearly focused on the youngest. Well, in the framework of this environment Philip Morris International - Coltabaco have created a promotional stand with promoter models for IQOS products and their HEETS derivative.

Philip Morris International - Coltabaco introduced the products IQOS - HEETS to the Colombian market in 2017; the launch (it was announced) would take place at the Estéreo Picnic 2017 Musical Festival on the 23, 24 and 25 of March, which, as recreated in the following paragraphs, are products that must observe the prohibitions of advertising, promotion and sponsorship of tobacco products and their derivatives (...).

On repeated occasions, spokespersons for Philip Morris International - Coltabaco have delivered statements in the media regarding the IQOS HEETS products, and notes have been published in which it can be clearly red that one product derives its use from the other. IQOS is a device used for heating and consuming the tobacco called HEETS, which is designed to be used exclusively with the IQOS device. IQOS derives its use from HEETS that also derives its use from IQOS, one cannot be used without the other.

(...) "

That taking into account that Mr. JAIME HERNAN ARCILA SIERRA sent a copy of his petition to the OMBUDSMAN'S OFFICE and to the OFFICE OF THE INSPECTOR GENERAL, these entities proceeded to transfer it to this Office, through the official letters filed with No. 17-401823-1 of January 4, 2018 (fls. 218 to 234), and the file No. 17-401823-2 of January 15, 2018 (fls. 235 to 251), respectively.

That subsequently, this Directorate made an administrative inspection visit to the website https://co.iqos.com/, with the purpose of verifying the information consigned in relation to the services offered by them, which was filed with No. 17-082520-18 of September 12, 2018.

That this Directorate became aware of the complaint filed under No. 19-087401-0 of April 12, 2019 (fls. 254 to 268), presented by Mr. NICOLÁS PARRA CASTRO, in his capacity as a member of the Educar Consumidores team, which is based on the following facts:

- 1. PHILIP MORRIS INTERNATIONAL acquired COLTABACO S.A.S, in the year 2005 and was constituted under the name of PHILIP MORRIS S.A in the country.
- 2. As part of the PHILIP MORRIS INTERNATIONAL's marketing strategy, this company ventured into the emerging market of smoking electronic devices and in this sense developed the product IQOS, which is an electronic device by which a vapor of tobacco is inhaled, which is heated through a metallic sheet.
- 3. The IQOS works by inserting a cylindrical tube of compressed tobacco called HEETS, which is very similar to a conventional cigarette and that produces tobacco vapor, which is inhaled by the consumer.
- 4. PHILIP MORRIS INTERNATIONAL chose Colombia to start the commercialization of IQOS in Latin America, which is carried out by COLTABACO S.A.S.
- 5. COLTABACO made a public launch of the IQOS product in the Estéreo Picnic 2017 Festival, held in the city of Bogota on the 23, 24 and 25 of March, 2017, and which immediately began to be marketed together with the HEETS product through electronic platforms and different sale spots located in shops and shopping centers.
- 6. Being a product made from tobacco leaf, HEETS must comply with each one of the rules contemplated in the legal system regarding tobacco control, norms that are composed by the Framework Convention on Tobacco Control (FCTC), the Law 1335 of 2009, and the rulings issued by the Constitutional Court in this regard, among which the judgment C-830 of 2010 stands out in terms of advertising, promotion and sponsorship.
- 7. Despite the fact that there is an international treaty and a national law that prohibits explicitly the advertising, promotion and sponsorship of tobacco, these regulations have not been applied to the IQOS, so today this product is advertised and promoted openly through various networks of communication to potential consumers. SOME PICTURES ARE ATTACHED IN THIS PETITION, SHOWING THE ADVERTISING AND PROMOTION FOR IQOS THROUGH MASSIVE EVENTS AND SOCIAL NETWORKS.
- 8. The prohibition of advertising, promotion and sponsorship of tobacco products also apply to the IQOS. The paragraph C of article 1 of the Framework Convention on Tobacco Control, ratified by Colombia through Law 1109 of 2006, defines tobacco advertising and promotion as follows: "tobacco advertising and promotion" means any form of communication, recommendation or commercial action with the purpose of, the effect or the possible effect to promote DIRECTLY OR INDIRECTLY A TOBACCO PRODUCT OR THE USE OF TOBACCO".
- 9. IQOS clearly promotes indirectly a tobacco product and its use, by which it is advertising and promoting a tobacco product.

Petition

1. We request the gentlemen of the Industry and Commerce Superintendency to demand to COLTABACO SAS and PHILIP MORRIS INTERNA TIONAL

COLOMBIA S.A the immediate cease of any type of advertising, promotion and sponsorship of the IQOS product in the Colombian territory.

- 2. Make use of their constitutional and legal powers to ensure that IQOS is not published, promoted or sponsored in any way in the Colombian territory.
- 3. Apply the total prohibition of advertising, promotion and sponsorship of tobacco products contained in the Framework Convention on Tobacco Control and the Law 1335 of 2009 to the IQOS product, marketed by COLTABACO.
- 4. In accordance with the powers of the Industry and Commerce Superintendency, guarantee the protection of the consumers' rights to health, since IQOS is a product that represents possible risks to the consumers' health.

 (..)

That among the documentation provided by the complainant the following is contained:

- 1. Photograph taken at the IQOS stand located in Santa Market Parque de la 93. Photo taken on November 27, 2017. Time: 11:23 AM. (fl. 256),
- 2. Photograph taken on March 24, 2017 at the Estéreo Picnic Festival where the IQOS promotional stand is visible (fl. 257).
- 3. Photograph taken on March 24, 2017 at the Festival Estéreo Picnic of an IQOS advertising balloon (fl. 258).
- 4. Invitation from IQOS to the VIP area of the Purple Beach Cartagena event. (ft. 259).
- 5. Photographs of Purple Beach Cartagena on January 3, 2019 (fl. 260).
- 6. Photograph taken on January 17, 2019, of an IQOS commercial stand in the Parque Colina Mall (fl. 261).
- 7. Cigarette box with the advertising insert: "discover a future without fire, start heating, stop burning" (fl. 262).
- 8. Photograph in the "Solar Festival Medellin" on March 1, 2019, in which the phrase IQOS appears (fl. 263).
- 9. Screenshot of the RAPPI application in which they offer the sale of the IQOS product (fl. 264).
- 10. Copy of the advertising pieces of the IQOS product on social networks (fls. 265, 266 and 267).

That, successively, this Directorate proceeded to make another administrative inspection visit to the website: www.iqos.com, which was filed with No. 17-082520-19 of May 9, 2019.

That when identifying that on the electronic platform www.iqos.com, the company PHILIP MORRIS COLOMBIA SA appears as the website owner and administrator, this Directorate proceeded to require it through the official letters No. 17-82520-20 and 17-82520-21 of May 15, 2019, in order to provide the following information:

"Inform whether they market the products called" IQOS "and "HEETS" in Colombia, hereinafter the products, and if so:

1. Describe each product and its presentations on the market.

- 2. Attach the technical data sheet of the products.
- 3. Indicate if any event in Colombia has been sponsored under the name of these products, and if the answer is affirmative, indicate which events and provide the advertising pieces and other documents related to them.
- 4. Send all the advertising pieces through which the products were offered and/or are offered, indicating the channels and the frequency with which they are broadcasted.
- 5. Inform from which date and through which channels the products are marketed.
- 6. Attach an importation certificate issued by the DIAN regarding the products.
- 7. Provide a copy of the authorization issued by the Ministry of Health and Social Protection for the labeling of products.
- 8. Attach a copy of each pack of the products. (...) "

That this Directorate also proceeded to require the COMPAÑIA COLOMBIANA DE TABACO S.A.S through official letters No. 17-82520-22 and 17-82520-23 of May 15, 2019, in order to inform the following:

"In relation to the preliminary investigation indicated under the filing number of the reference, this Directorate orders to submit a copy of all the physical and digital advertising pieces through which the products called IQOS and HEETS were offered and/or are offered, indicating the channels and the frequency with which they are emitted.

(...) "

After having been granted an extension request, the company COMPAÑIA COLOMBIANA DE TABACO S.A.S. sent a document filed with No. 17-082520-36 of May 29, 2019, that presents the advertising pieces, physical and digital, through which the IQOS product has been offered. It also states that, regarding HEETS, "it is worth clarifying that the company has not advertised this product". Thus, the company COLTABACO S.A.S provided a copy of a CD available on page 349, which consists of a Power Point document that contains the advertising pieces of the product IQOS.

That, for its part, the company PHILIP MORRIS COLOMBIA S.A provided a response to the request for information through the document filed with No. 17-082520-37 of May 29, 2019, where it states the following:

"(...)

Regarding the requirement presented, allow me to clarify that the company Philip Morris Colombia S.A, has been marketing HEETS, IQOS and IQOS accessories in Colombia only since April twenty-two (22), 2019.

(...)

IQOS is an electronic tobacco heating device, which is designed not to create combustion or smoke, but to generate heat to produce aerosol.

Currently, three (3) references of the IQOS product are commercialized in the Colombian market, which are IQOS 2.4 +, IQOS 3 and IQOS 3 Multi. IQOS 2.4 + and IQOS 3 are made up of two main elements: (i) an electronic tobacco heating device, and (ii) an electronic charger to recharge the device, while IQOS 3 Multi consists of a single element that contains both heating and electronic charging functions. The device, the technical description of the heating system and the instructions for use that describe and illustrate its operation are presented in the annex No.1.

(...)

HEETS are tobacco consumable units, specially designed to be inserted into the IQOS heating device. When the IQOS device heats the HEETS, an aerosol is generated that can be inhaled.

The HEETS do not light or burn, so they do not generate smoke, unlike what happens with a cigarette when it is smoked. HEETS are not cigarettes, they are not smoked and are also not lighted, which puts them in a different category.

 (\dots)

PMC has not sponsored any event in Colombia under the name of the IQOS and HEETS products.

(...

IQOS is an electronic device and as such it is not subject to the advertising limitations established in the Law 1335 of 2009. Based on this, all the publicity of this products that PMC has made is presented in the attached CD. (...)

In relation to HEETS, NO advertising has been made nor have any publicity pieces that contain the HEETS brand or images been produced.
(...)

PMC began the commercialization of IQOS and HEETS on April 22, 2019. The channels used are: (i) business premises in which IQOS and HEETS are commercialized; (ii) big-box stores in which HEETS are commercialized; (iii) through the "Rappi" delivery technological platform, in which HEETS, IQOS and IQOS accessories are commercialized; finally (iii) on the www.iqos.com website, where it is possible to request a visit from an "IQOS EXPERT" who will provide the interested consumer of legal age with instructions on how to use the device and with the possibility of purchasing it at that time.

PMC is exclusively dedicated to the commercialization of the products inside the national territory since April 22 of the current year, according to this, PMC has not requested authorization to the Ministry of Health and Social Protection for the labeling of the products because it does not correspond to it. The authorizations from the Ministry of Health and Social Protection for the labeling of the products were emitted to the Compañía Colombiana de Tabaco SAS, who oversaw importing and commercializing the product at that time.

(...)

As attached documentation, the company PHILIP MORRIS COLOMBIA S.A provided:

- 1. An IQOS device and its instructions for use (fl. 355).
- 2. The HEETS product data sheet (fls. 356- 357).
- 3. Publicity material issued by PMC in relation to IQOS (CD on fl. 358).
- 4. Presentations of references for the HEETS product (fls. 359 to 365).

That, subsequently, this Directorate, through the memorandums filed with the numbers 17-82520-38, 17-82520-39 and 17-82520-40 of July 5, 2019 (fls. 366 to 374), asked the Ministry of Health and Social Protection, in its capacity as rector of public policies in health, to provide the following information:

- Indicate what the public policy of the Ministry of Health and Social Protection consists of, in the area of prevention of tobacco consumption and the abandonment of the tobacco -and its derivatives- dependence on smokers in the Colombian population, regarding Electronic Nicotine Administration Systems (ENAS), Electronic cigarettes, Heated Tobacco Products (HTP) and the other devices employed for its use.
- Inform whether the Ministry of Health and Social Protection, in the scope of its powers, is applying Law 1335 of 2009 and the Resolution No. 3961 of 2009 regarding the Electronic Nicotine Administration Systems (ENAS), Electronic cigarettes, Heated Tobacco Products (HTP) and the other devices employed for its use.
- Inform whether the prohibitions contained in Law 1335 of 2009 and the dispositions of the Resolution No. 3961 of 2009, are applicable to Electronic Nicotine Administration Systems (ENAS), Electronic cigarettes, Heated Tobacco Products (HTP) and other devices employed for its use.
- Indicate whether COMPAÑIA COLOMBIANA DE TABACO S.A.S. COLTABACO SAS or the company PHILIP MORRIS COLOMBIA S.A., has requested before you the authorization for the labeling of the products IQOS and HEETS referred to in Article 6 of Resolution 3961 of 2009, in other words, if they have submitted before the General Directorate of Public Health of the Ministry of Health and Social Protection, the color proofs and a simulation of the finished product, respecting all its characteristics of color, design, proportions and others, for each warning and each packaging presentation.

That in addition to the above, this Directorate, as an annex to the request of information sent to the Ministry of Health and Social Protection, provided a copy of the document called: "Request of information made to the International Network of Consumer Protection Agencies (INCPA) regarding the regulation of 'Heated Tobacco Products' in their jurisdictions", which contains the compilation of responses from its members until July 3, 2019, that are presented bellow:

"(...)

I. Response sent by the Federal Consumer Attorney (PROFECO, for the acronym in Spanish) of the United States of Mexico.

"(...) In Mexico, the General Law for the Control of Tobacco (attached), implemented by the Secretary's Office of Health, is the one that governs the advertising, packaging and labeling of tobacco products.

In its article 16. "(...) any object other than a tobacco product, that contains any of the elements of the brand or any type of design or auditory signal that identifies it with tobacco products, is prohibited." This provision means that the sale of electronic cigarettes is prohibited in our country. The same principle applies to the heated tobacco products ". (...)"

(...)

- II. Response sent by the Federal Ministry of Justice and Consumer Protection of the Federal Republic of Germany.
 - "(...) regarding the enforcement of the consumer law, we have rarely addressed the issue of Heated Tobacco Products. We are not responsible for regulating tobacco products, we regret not being able to contribute on this issue.
- III. Response sent by the Protection Center to the Consumers Rights of the Republic of Latvia.
 - "(...) In Latvia we have a law for the handling of tobacco products, herbal products for smoking, electronic smoking devices and their liquids "(there is an updated version of the law in English: https://likumi.lv/ta/en/en/id/282077-on-the-handling-of-tobacco-products-herbal-products-for-smoking-electronic-smoking-devices-and-their-liquids)

The main provisions of the law are:

Labeling and packaging: section 6. Presentation of tobacco products, herbal products for smoking, electronic cigarettes, refill containers; appearance and content of the packages per unit.

(...)

- *3). Warnings for specific risk groups;*
- 4). Possible side effects
- 5) Addictiveness and toxicity;
- 6) Contact information of the manufacturer or importer and of juridical or natural persons within the European Union and the European economic integration.
- 7) A unitary package of cigarettes must have the shape of a cube, (...)

 (\dots)

- 1) Health warnings in the official language will be put on each unitary package of the commercialized tobacco product, product based on herbs for smoking, electronic cigarettes and refill containers.
- 2) The following health warnings will be printed on each unitary package and on any outer wrapping of a smoking tobacco product.
 - 1. General warning: "Smoking kills, quit it now!"
 - 2. Informational message. ' "Tobacco smoke contains more than 70 substances known to cause cancer",
 - 3. Combined health warning that has been supplemented with the following information on smoking cessation:
 - "ask for help! 67037333; www.spkc.gov.lv"

- 3) The following health warning will be print on each unitary package and in any wrapping and exterior of a tobacco product without smoke: "This tobacco product is damaging to your health and is addictive."
- 4) The following health warning will be printed on each unitary package and in any outer packaging of a product based on herbs for smoking: "smoking this product damages your health."
- 5) The following health warning will be printed on each unitary package and in the outer packaging of an electronic cigarette and a refill container: "This product contains nicotine, which is a highly addictive substance".

(...)

- IV. Response sent by the National Commission for the Consumer of the Republic of South Africa
- "(...) In response to the investigation sent through the ICPEN Secretary's Office, please note that in South Africa tobacco is a regulated product included in the scope of the National Department of Health (http://www.health.qov.za). The Law of Control of Products of Tobacco (Law 83 of 1993) modified by: Law 12 of 1999; Law 23 of 2007 and Law 63 of 2008, prohibits or restricts smoking in public places; regulates the sale and advertising of tobacco products in certain aspects and prescribes what must be reflected in the packages and related issues. Key areas in the legislation include:
 - Standards for manufacturing and export
 - Advertising and packaging
 - Public places
 - Health warning signs
 - Age restrictions and exposure of children to tobacco smoke
 - In the work place. (...) "

(...)

V. Reply sent by the Ombudsman of the Danish People of the Kingdom of Denmark. "In Denmark, heated tobacco products are taxed as smoking tobacco and are covered by the Tobacco Advertising Act (Law no. 1021 of 21/10/2008). Distributors must not promote heated tobacco products, and in Denmark the Ombudsman of the Danish Consumer oversees the tobacco publicity. The law of tobacco products (Law No. 608 of 7/06/2016) regulates the health warnings on tobacco products and the labeling and packaging of tobacco products (...)

(...)

- VI. Response sent by the Commission on Competition and Consumer Protection of the Republic of Ireland
- "(...) Commission on Competition and Consumer Protection (Ireland) is not involved in the regulation of tobacco products. The relevant authority in Ireland is the Department of Health, and information related to the standardization of packages of cigarettes, including information on the applicable legislation, be can be found on their website through the following link:

https://health.gov.ie/healthv-ireland/tobacco/standardisedplain-pack-cigarettes/ (...)"
(...)

VII. Response sent by the General Directorate of Public Health and Quality of Life addressing dependencies of the Hellenic Republic.

The legislation in force in Greece consists of

• Directive 2014/40/EU of the European Parliament and Council, of April 3, 2014, relative to the approximation of the legal, regulatory and administrative provisions of the Member States on the manufacture, presentation and sale of tobacco and related products, with which the Directive 2001/37/EC is repealed.

This regulation is implemented in our Greek legislation by means of the following rulings:

Law No. 4419/2016 (Government Newspaper 174 / A / 20.11.2016) "Adaptation of Greek legislation to Directive 2014/40/EU of the European Parliament and European Council and of the European Commission on April 3, 2014, on the approximation of Laws, regulatory and administrative rulings of the Member States regarding manufacturing, presentation and sale of tobacco products, related products, and to the suppression of the 2001/37/EC (DO L 127/1 of 29-4.2014) as the Annex II of said Directive, modified by Directive 2014/109/EU of the Delegated Commission of October 10, 2014, for the modification of Annex I of Directive 2014/40/EU of the European Parliament and Council with the establishment of the warning pictograms library that should be used for tobacco products, and other relevant rulings".

VIII. Response sent by the Department of Protection of the Consumer and of any business fraud of the State of Qatar.

"(...) On behalf of the Director of the Department for the Protection of the Consumer and Business Fraud, regarding an email on the requirements for the regulation of marketing, packaging and labeling of heated tobacco products.

In Qatar we have a legal regulation on tobacco control and its derivatives, which are mentioned in Law no. 10 of 2016. This Law is monitored by the Ministry of Public Health.

In addition, the Ministry of Commerce and Industry has issued a ministerial decree No. (341) of 2016 regarding the requirements and controls that must exist in the stores that provide tobacco and tobacco products. This decree is monitored by the licensing department of our Ministry. (...)"

That in addition to the above, this Directorate filed with number 17-082520-41 of July 9, 2019, the compilation of the responses presented by INCPA members to the request of information formulated regarding the regulation of "Heated Tobacco Products" in their jurisdictions, in the original language.

That the Directorate of Promotion and Prevention of the Ministry of Health and Social Protection, as agency in charge of public policy actions for tobacco control, through the document filed with No. 19-183640-0 of August 15, 2019, provided a response to the request of information sent by this Directorate through the memorandums filed with the

numbers 17-82520-38, 17-82520-39 and 17-82520-40 of July 5, 2019, in which it stated, among other things, the following:

"(...) this Ministry, from the joint construction of the Public Health Plan for the Decade 2012-2021, positioned within the political agenda the importance of addressing non-transmittable diseases, which are related, as already mentioned, with the highest mortality rates in the world and in Colombia. For this reason and against this background, the dimension "healthy life and non-communicable conditions" is established within the structure of the plan. This dimension raises, in turn, two major components for its development: i) healthy ways, conditions and lifestyles and ii) prevailing chronic conditions. The first component sets four goals related to the promotional strategy for the prevention of tobacco consumption, which are:

- 1. By 2021, reduce smoking by 10% in people aged 18 to 69.
- 2. By 2021, postpone the age of onset of tobacco use in the Colombian teenagers to over 14 years old.
- 3. By 2021, increase in 100% the taxes indexed according to the Consumer's Price Index (CPI) and the Gross Domestic Product (GDP) for the tobacco products and their derivatives.
- 4. By 2021, achieve the compliance of environments 100% free of tobacco smoke and its derivatives at the national level, in the places defined by Law 1335 of 2009.

(...)

In addition to the above, another instrument of public policy that has established, from the health sector, the importance of promotion, prevention and care for non-transmittable diseases is the Ten-Year Plan for the control of cancer in Colombia (2012-2021), which is a development of the health policy in the country and recognizes the causal relationship between tobacco use and the development of these serious and costly diseases.

(...)

In the case of Heated Tobacco Products HTP, it is important to note that this Ministry, in a communication (attached) dated to March 5, 2018, sent the technical concept of HEETS Heated Tobacco Products and their IQOS heating device to the Directorate of Taxes and National Customs DIAN, where it clearly stated that these devices, regardless of how they are lighted, are covered by the tobacco control legislation. All in all, and as will be seen further on, this Ministry has demanded the labeling and packaging requirements for tobacco products and its derivatives to the HEETS, that is to say, to the compressed tobacco columns, but not to IQOS devices. However, given the health consequences of these new devices, the latest global report on the smoking epidemic 2019 (WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC 2019) includes a chapter on the subject, highlighting, for example, aspects of the nature of the product, its harmfulness and regulatory aspects, as follows: Heated tobacco products (HTPs) are tobacco products that produce aerosols containing nicotine and toxic chemicals upon heating of the tobacco or activation of a device containing the tobacco. These aerosols are inhaled by users during a process of sucking or smoking involving a device. They contain the highly addictive substance nicotine, non-tobacco additives and are often flavoured. The tobacco may be in the

form of specially designed cigarettes (e.g. "heat sticks", "Neo sticks") or pods or plugs.

HTPs differ not only to conventional cigarettes, but also to electronic nicotine delivery systems (ENDS, some of which are called e-cigarettes), as ENDS do not contain tobacco, but rather a nicotine solution. These boundaries, however, are increasingly difficult to define. (...)

HTPs are tobacco products. This means that Parties' obligations under the WHO FCTC apply to HTPs in the same way as they apply to conventional cigarettes. MPOWER measures help WHO Member States to implement the demand reduction articles of the WHO FCTC and are equally applicable to HTPs as they are to other tobacco products.

(...)

Now, regarding the specific measures that should be considered in the internal legislation, the WHO recommends taking into account:

1. Regarding the promotion and advertising:

All forms of advertising, promotion and sponsorship of ESAN must be regulated by a competent government agency. If not possible, a total prohibition of any kind of advertising, promotion and sponsorship of ESAN would be preferred to the application of volunteer codes on the commercialization of ESAN, in view of the overwhelming evidence showing that similar codes for tobacco products and alcohol have not served to protect young people against such advertising.

(...)

Conclusions

- There exist a large and diverse number of new tobacco products and others that simulate the action of smoking in the Colombian market.
- The existing regulation covers all tobacco derivate products including heating tobacco products as a complex product.
- The products called Electronic Systems of Administration of Nicotine ESAN, and without supply of Nicotine ESWSN, are not included in the existing legislation for tobacco control in the country; however, as products for human consumption, the set of rules related to quality and information enforced to all consumer goods is applicable.

(...)

The company COLTABACO S.A.S has been presenting to this Ministry the simulations corresponding to the IQOS - HEETS products, from the 2018-2019 period. The description of the requests of information is exposed in the following table:

Validity	Application filing	Products	Response filing
2018-2019	201842300003832 of January 2, 2018	HEETS TURQUOISE LABEL X 20 units	201821200241911 of February 28, 2018
		HEETS BLUE LABEL X 20 units	
		HEETS AMBER LABEL X 20 units	

		HEERS TURQUOISE LABEL X 200 units	
		HEETS BLUE LABEL X 200 units	
		HEETS AMBER LABEL X 200 units	
	201842300470392 of April 4, 2018	HEETS TURQUOISE LABEL X 20 units	N/A
		HEETS BLUE LABEL X 20 units	
		HEETS AMBER LABEL X 20 units	
		HEERS TURQUOISE LABEL X 200 units	
		HEETS BLUE LABEL X 200 units	
		HEETS AMBER LABEL X 200 units	
	201942300101922of January 25, 2019.	HEETS AMBER 20S	201921200206051 of February 20, 2018
		HEETS AMBER BOX	
2019-2020		HEETS YELLOW 20S	
		HEETS YELLOW BOX	
		HEETS BRONZE 20S	
		HEETS BRONZE BOX	
		HEETS SIENNA 20S	
		HEETS SIENNA BOX	
		HEETS TURQUOISE 20S	
		HEETS TURQUOISE BOX	
		HEETS BLUE 20S	
		HEETS BLUE BOX	
		HEETS PURPLE 20S	
		HEETS PURPLE BOX	
	201942300937302	HEETS GREEN ZING 20S	201921200912151
	of June 14, 2019	HEETS GREEN ZING BOX	of July 16, 2019

The filings are attached, along with the corresponding samples and it should be noted that all the simulations presented were approved."

That, subsequently, this Directorate required the COMPAÑIA COLOMBIANA DE TABACO S.A.S and the company PHILIP MORRIS COLOMBIA S.A, through official letters No. 17-82520-42 and 17-82520-43 of September 13, 2019, and 17-82520-44 and 17-82520-45 of September 13, 2019, respectively, to provide the following information:

"(...)

- 1. Indicate which are the events, regardless of their nature, that the company has organized, carried out and sponsored during the year 2019.
- 2. Provide all the advertising pieces, regardless of the channel of dissemination (radio, television, press, website, outdoor advertising, social networks, among

others), through which each one of the events mentioned were sponsored, indicating the frequency, the announcement channels and the last date they were published or broadcasted.

- 3. Indicate, in relation to each of the events that have taken place during the year 2019, the following:
- a. Who was the organizer of the event?
- b. Who were the sponsors of the event?
- c. What was the event about?
- d. What was the objective of the event?
- e. On what date did the event took place?
- f. List the panelists invited to the event
- g. Which topics were discussed at the event
- h. Inform to which public the event was directed and who were the attendees.
- 4. List which are the events, regardless of their nature, projected to be carried out and/or become sponsored by the society in the next six (6) months.
- 5. Deliver all the advertising pieces, regardless of the channel of divulgation (radio, television, press, outdoor advertising, website, social networks, among others), through which each of the events to be held in the next six (6) months is being promoted, listing the following:
- A. Who is the organizer of the event?
- B. Who are the sponsors of the event?
- C. What is the event about?
- D. What is the objective of the event?
- *E.* What is the date of the event?
- F. List the panelists who will be invited to the event
- *G.* What are the topics to be discussed at the event?
- H. Inform to which public the event is aimed at and who will be the attendees. (...) "

That the company PHILIP MORRIS COLOMBIA S.A filed a response to the request of information with the document filed with No. 17-082520-46 of October 1, 2019, stating that: "PMC company has not held or sponsored any event so far in 2019, nor does it plan to carry out, organize or sponsor events in the next six (06) months."

That subsequently, the company COLTABACO S.A.S filed a response to the request through official letter No. 17-082520-47 of October 1, 2019, in which it states the following:

"(...) To respond to the information requested in numerals 1, 2 and 3, a DVD is attached containing the documents with the detailed required information.
(...)

Coltabaco has an internal approval process in which the commercial events to be held each month are reviewed and approved, which is why we do not have information about the events planned for the next 6 months.

For non-commercial events held for consumers, a DVD containing documents with the detailed information required is attached. "

That, under what is set forth in paragraph 1, article 36 of Law 1437 of 2011¹, this Directorate proceeded to accumulate the actions identified with the files: 17-401823, 19-087401, 19 183640 to this administrative action (17-082520), as long as they meet with the proper requirements for such procedure (accumulation).

That this Directorate, prior to issuing a pronouncement on the present matter, considers pertinent to make the following considerations:

a) Considerations about the competence of the Superintendency of Industry and Commerce regarding the IQOS product.

The Superintendency of Industry and Commerce is competent to know about the infractions set forth in Law 1335 of 2009, regarding the control and prohibition of advertising, promotion and sponsorship of tobacco, by virtue of the provisions of numeral 9 of article 12 of Decree 4886 of 2011, that establishes within the assigned functions to the Directorate of Investigations of Consumers Protection the following:

"Article 12. Functions of the Directorate of Investigation of Consumers **Protection**. They are functions of the Directorate of Investigations of Consumers Protection:

(...)

9. Exercise the functions established in Law 1335 of 2009, and in the ones that modify, add, or regulate it, in terms of advertising, packaging and prohibition of promotion and sponsorship of tobacco and its derivatives.

(....) "

Meanwhile, Law 1335 of 2009 states "the provisions through which health damages in minor and non-smoker population are prevented, and the public policies stipulated for the prevention of tobacco consumption and the abandonment of the smoker's dependence of tobacco and its derivate in the Colombian population" and regarding the objective set out in article 1 it is intended: "to contribute to guarantee the rights to health of the inhabitants of the national territory, especially those under 18 years of age and the non-smoking population, regulating the consumption, sale, advertising and promotion of cigarettes, tobacco and its derivatives", from which it is deduced that the scope of application of the norm is circumscribed to the prohibition of all types of advertising, promotion and sponsorship of the tobacco products and their derivatives. That prohibition is stated in articles 14, 15 and 16 of the Law 1335 of 2009, which are transcribed below:

"ARTICLE 14. CONTENT IN THE CHANNELS OF COMMUNICATION AIMED TO THE GENERAL PUBLIC. Any natural or legal person can, de facto o de jure, promote tobacco products on radio, television, film, written media such as newsletters, newspapers, magazines or any mass diffusion document, theatrical

¹Article 36. Formation and examination of files. The documents and reports related to the same action will be organized in a single file, in which will be accumulated, in order to avoid contradictory decisions, of office decisions or at the petition of the interested party, any others that are processed in the same authority.

productions or other live performances, live or recorded musical performances, video or commercial films, compact discs, digital video discs or similar media. PARAGRAPH. Cable operators, satellite operators and community television operators that are duly authorized to the National Television Commission, through license, will not allow the emission in Colombia of commercials or tobacco advertising produced abroad.

The penalties will be the same as those provided in this Law.

ARTICLE 15. ADVERTISING IN FENCES AND SIMILAR. It is forbidden to all natural or legal person the setting of fences, banners, murals, posters or similar, mobile or fixed, relating to the promotion of tobacco and their derivatives. ARTICLE 16. ADVERTISING. All forms of advertising of tobacco products and their derivatives are forbidden."

Meanwhile, it should be noted that in the scope of application of Law 1335 of 2009, the inclusion of the devices called "Heated Tobacco Products (HTP)" was not foreseen, among which the IQOS product can be found, which according to the World Health Organization - WHO have the following characteristics:

IQOS is a Heated Tobacco Product (HTP) that heats nicotine through a device. In what follows, the definition given by the WHO on the Heated Tobacco Products (HTP) is transcribed:

"Heated tobacco products (HTPs) are tobacco products that produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. They contain the highly addictive substance nicotine (contained in the tobacco), which makes HTPs addictive. They also contain non-tobacco additives, and are often flavored. HTPs mimic the behavior of smoking conventional cigarettes, and some make use of specifically designed cigarettes to contain the tobacco for heating."²

That the WHO further warns that the IQOS products marketed by PHILIP MORRIS INTERNATIONAL can be found within the Heated Tobacco Products:

" What are some examples of HTPs?

There are a number of these tobacco products available on several markets.

Examples include iQOS from Philip Morris International, Ploom TECH from Japan Tobacco International, Glo from British American Tobacco, and PAX from PAX Labs."³

The WHO also points out that the role of the HTPs is developed as follows:

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 $^{^2}$ Retrieved from: https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/es/ on 8/05/2019 at 11:26 am

³ Ibídem

" How do HTPs work?

In order to produce the nicotine-infused vapor, HTPs heat tobacco up to 350°C (lower than 600°C as in conventional cigarettes) using battery-powered heating-systems. The heating-system enclosed in a device, can be an external heat source to aerosolize nicotine from specially designed cigarettes (ex. iQOS and Glo), or a heated sealed chamber to aerosolize nicotine directly from tobacco leaf (ex. Ploom and Pax).

The heating device requires charging and the user draws on the mouthpiece at intervals to inhale volumes of the aerosol through the mouth, which is then taken into the body."⁴

It is necessary to clarify that according to the WHO the IQOS products, considered as HTPs, are not electronic cigarettes:

" Are HTPs electronic-cigarettes?

No, HTPs are not e-cigarettes. HTPs heat tobacco to generate nicotine. E-cigarettes heat e-liquid, which may or may not contain nicotine and in most cases do not contain tobacco."⁵

Taking into account the considerations of the World Health Organization regarding the HTPs, and considering that the scope of the application of Law 1335 of 2009 is limited to the prohibition of all types of advertising, promotion and sponsorship of tobacco products and its derivatives, it is necessary to indicate at this point that the IQOS product, as it was defined by the WHO, as a heated tobacco product, by itself does not contain tobacco, as it constitutes a heating device powered by a charger, which does not contain tobacco.

This is how the Ministry of Health and Social Protection, as the agency in charge of the public policy actions for tobacco control, by means of a document filed with No. 19-183640-0 of August 15, 2019, indicated to this Directorate of Investigations of Consumer Protection, that has demanded the requirements for labeling and packaging of products of tobacco and its derivatives to the products called HEETS, but not to the IQOS device. The following is a transcription of what was indicated by the Ministry of Health and Social Protection:

"In the case of Heated Tobacco Products (HTP), it is important to note that this Ministry, in a communication dated March 5, 2018 (attached), sent a technical concept on the heated tobacco products HEETS and its IQOS heating device to the Directorate of Taxes and National Customs DIAN, where it expressly stated that these devices, regardless of their ignition form, are included in the legislation of tobacco control. Now, and as will be seen later, this Ministry has demanded the labeling and packaging requirements of tobacco products and their derivatives to HEETS, that is to say to the columns of compressed tobacco, but not to IQOS devices.

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⁴ Ibídem

⁵ Ibídem

(...)"

In that vein, it is necessary to state now that despite the competence assigned to the Directorate of Investigations of Consumer Protection by article 12 numeral 9 of Decree 4886 of 2011, to examine the infractions contained in Law 1335 of 2009 and to apply the sanctions set forth there, in terms of advertising, packaging and prohibition of promotion and sponsorship of tobacco and its derivatives, it is considered by this Directorate that the IQOS device is not included in this prohibition since it does not constitute a tobacco product or derivative of it, according to the definition provided by the Law 1109 of 2006, "by means of which the WHO Framework Convention on Tobacco Control is approved", which in its article 1 letter f provides the following:

"Article 1

List of expressions used

For the purposes of this Convention:

f) "tobacco products" means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing;

(...) "

Thus, tobacco products include those prepared totally or partially using tobacco leaves as raw material and that also are intended to be smoked, sucked, chewed or used as snuff, which does not agree with the definition given to the IQOS devices as these constitute a heating system that must be charged by means of electric current. Different situation is that in its use the products called HEETS are inserted. Consequently, this Directorate considers that the IQOS product is not included within the restrictions contained in Law 1335 of 2009.

b) Considerations regarding the Principle of Legality

The Superintendency of Industry and Commerce, in its capacity as administrative authority, exercises the competences in matters of infringement of the Law 1335 of 2009, by virtue of the mandate established in article 1, numeral 26, of Decree 4886 of 2011, which establishes that this authority shall: "exercise the functions established in Law 1335 of 2009 and those that modify, add, or regulate it, in terms of advertising, packaging and prohibition of promotion and sponsorship of tobacco and its derivatives."

That by virtue of the above, the applicable sanctioning procedure for the imposition of penalties derived from Law 1335 of 2009, that is carried out by the Superintendency of Industry and Commerce, is the one provided in Chapter III of Law 1437 of 2011, Code of Administrative Procedure and of Administrative Litigations, in articles 47 and the following ones. In that procedure the principles of legality of the faults and offenses, the presumption of innocence, non reformatio in pejus and non bis idem as established in incise 2 of numeral 1 of article 3 of Law 1437 of 2011 must apply. Said article 3 establishes the following:

"ARTICLE 30. PRINCIPLES. All the authorities shall interpret and apply the provisions that regulate the legal actions and administrative procedures considering the principles established in the Political Constitution, in the First Part of this Code and in the special laws:

(...)

1. By virtue of the principle of due process, the administrative proceedings will be carried out in accordance with the procedure and competence legal norms established in the Constitution and the law, with the full guarantee of the rights of legal representation, defense and contradiction.

In administrative sanctioning matters, the principles of legality of faults and sanctions, presumption of innocence, no reformatio in pejus and non bis in idem will be observed. "

That, regarding the principle of legality of faults and sanctions, the Constitutional Court in Sentence C-699 of 2015, has stated that:

The principle of legality assumes that a legal norm with material force of law establishes the description of the punishable behaviors, as well as the class and amounts of the sanctions to be imposed. In sanctioning matters, this principle also materializes in the typicality, but with different application from the one that operates in criminal matters, because of not dealing with conducts that imply such a significant intrusion into the hard core of the fundamental rights. That is to say, that its more burdensome implications do not extend to the restriction of rights such as freedom. In this regard, in the Judgment C-242 of 2010, by which the third paragraph of Article 175 of Law 734 of 2002 was declared in accordance with the Constitution, this Court stated:

"In the field of administrative sanctioning law, the principle of legality is applied less rigorously than in criminal matters, due to the distinctive features of the sanctioning regulations, for the consequences arising from its application, the purposes they pursue and the effects they produce over people. From this perspective, the administrative sanctioning law usually contains rules with a broader degree of generality, which in itself does not imply a breach of the legality principle if there is a reference framework that allows to specify the determination of the infringement and the sanction in a particular matter. Thus, administrative sanctioning law is compatible with the Constitution if the norms that integrate it even if they are general and denote a certain degree of imprecision - do not leave the field open for the arbitrariness of the administration in the imposition of sanctions or penalties. Under this perspective, the principle of legality is fulfilled in the field of sanctioning administrative law when it is established: (i) "the basic elements of the offensive conduct that will be sanctioned"; (ii) "the precise normative references when a blank type has been set forth, or the criteria by

means of which the clarity of the conduct can be determined"; (iii) "the sanction that will be imposed or the criteria to determine it clearly."

(...)

The principle of legality requires that within the administrative sanctioning procedure the fault or reprehensible conduct is typified in the legal norm -lex scripta- previous to the facts subject of the investigation -lex previous-. This follows from the content of subsection 2 of Article 29 of the Political Constitution that establishes the principle of legality, by providing that "no one can be judged but according to the pre-existing laws to the act that is imputed (...) ", that is, there is no penalty or sanction if there is no law that determines the legality of said action."

Similarly, the Constitutional Court considers in Judgment C-739 of 2000 that the principle of typicality is implied within the principle of legality, and it considers about this topic that:

"Now, the principle of typicality implicit in that of legality refers to the obligation of the legislator to define with clarity and specificity the act, fact or omission constituting the conduct considered as offensive by the legal system, in a way that allows the people to whom the rules are directed to know prior to committing it the implications that their transgression carries. Regarding the scope of this principle, the Constitutional Court, through Judgment C-343 of 2006, stated the following reasoning:

"One of the essential principles included in article 29 of the Political Constitution is the principle of typicality, from which it is derived the "requirement of describing in a specific and precise way the legal norm that creates offenses and penalties, the conducts that may be sanctioned and the material content of the sanctions that may be imposed by the commission of each conduct, as well as the correlation between one and the other."

In this way, to satisfy the principle of typicality, the following elements must concur: (i) that the punishable conduct is described specifically and precisely, because it is determined in the same normative body or is determinable from the application of other juridical norms; (ii) that there is a sanction whose material content is defined in the law; (iii) that there is a correlation between the conduct and the sanction;"

In this order of considerations, <u>essential elements of the administrative</u>

<u>penalizing type are these: (i) the description of the conduct or the behavior that leads to the application of the sanction; (ii) the determination of the sanction, including the duration or its amount, (iii) the competent authority to apply it and</u>

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⁶ http://www.corteconstitucional.gov.co/RELATORIA/2015/C-699-15.htm.

(iv) the procedure to be followed for its imposition."⁷ (underlines and bold not included in the original text)

Likewise, the Constitutional Court in Judgment T-1087 of 2005, "when addressing the issue of favorability from the perspective of the principle of legality specified that "[since] the sanctioning authority of the administration is not foreign to the principles that rule the due process in a criminal matter, specifically to the requirement that a prior law must determine with clarity and precision both the offense and the penalty to be imposed on those who incur in it, it is possible to conclude that once a fault has been abolished, the penalizing effects that it could be producing must disappear as well".

Thus, in accordance with the aforementioned legal and constitutional principles, it is also not possible for this Directorate to give a different scope to Law 1335 of 2009, and to extend its application to the IQOS product.

b) Judgment of the Administrative Court of Cundinamarca

In line with the above, it is relevant to indicate that Mr. NICOLAS PARRA CASTRO, brought the action for enforcement of norms with force of law or administrative acts, before the Superintendency of Industry and Commerce so that this entity would comply with the following:

- "1. Apply the prohibition of advertising and promotion contained in the Article 13, and defined in letter C of Article 1 of Law 1109 of 2006 (FCTC) to IQOS, and consequently demand COLTABACO the immediate withdraw of all the media through which the IQOS is presented to the public or through which the product or brand is exhibited, and require it to abstain from future activities framed in the advertising and promotion of tobacco products or their derivatives.

 (...)
- 2. Apply the prohibition of advertising and promotion set forth in the Article 16 of Law 1335 of 2009, and consequently demand COLTABACO the immediate withdraw of all the media through which the IQOS is presented to the public or through which the product or brand is exhibited, and require it to abstain from future activities framed in the advertising and promotion of tobacco products or their derivatives.

The Administrative Court of Cundinamarca, First Section, Subsection B, with judgment of September 25, 2019, under file No. 25000-23-41-000-2019-00508-00, indicated that in order to proceed with the enforcement action, the following requirements must be observed:

"(...)

a. That the legal duty that is asked to be fulfilled is prescribed in applicable norms with material force of law or administrative acts (art. 1 Law 393 of 1997).

⁷ http://www.corteconstitucional.gov.co/RELATORIA/2015/C-699-15.htm# ftn74

- b. That the mandate is imperative and unobjectionable and that it is established at the head of that public authority or of an individual in exercise of public functions, to whom their fulfillment is claimed (arts. 5 and 6 ibidem).
- c. That the reluctance to the compliance of the duty is proven, occurred either by action or omission of who is required to comply, or by the performance of acts or facts that allow deducing its imminent incompletion (art. 8 of the same legal norm).
- d. That the duty whose fulfillment is claimed, prescribed in the legal norm with material force of law or administrative act, is legally valid and currently enforceable."

That, being the aforementioned requirements analyzed and contrasted with the legal norms allegedly breached by the Superintendency of Industry and Commerce, the H. Administrative Court of Cundinamarca considered the following:

"(...) In this sense, the Chamber notes that the letter c) of article 1, and Article 13 of the Law 1109 of 2006, and Article 16 of the Law 1335 of 2009 do not set forth an imperative, unobjectionable, precise and demandable mandate to the defendant entity, added to the fact that the requests of the plaintiff are ultimately directed to get an order for the Superintendency of Industry and Commerce to speed up an administrative action where it investigates some alleged irregularities related to the advertising and promotion of the device called IOOS by the Coltabaco S.A.S and Philip Morris Colombia SA companies, which is not regulated by any of the legal mandates mentioned by Mr. Nicolas Parra Castro as unfulfilled in the present case. For those reasons the claims of the lawsuit will be denied."

In accordance with the above, it is clear that the H. Administrative Court of Cundinamarca determined that, none of the mandates employed by the plaintiff, that is, neither the letter c) of article 1 and article 13 of Law 1109 of 2006, nor article 16 of Law 1335 of 2009, are imperative mandates in charge of this Superintendency. Consequently, and in accordance with the arguments presented already in relation to the principle of legality, this Superintendency asserts that it is not possible to apply the Law 1335 of 2009 to the heated tobacco product known as IQOS.

Thus, by virtue of the general principle of law that indicates that where the legislator did not make a distinction, it is not possible for the interpreter to create it, as well as the principle of legality of the faults and sanctions, which has implicit the principle of typicality, in merit of which exists an exclusive attribution by the Congress of the Republic, in its capacity as legislative body, to define clearly and specifically the "act, fact or omission constitutive of the behavior considered as offensive by the legal system, in a way that allows the people to whom the rules are aimed to know in advance to the commission of the implications of its breach" and; since it is not possible to the Superintendency of Industry and Commerce to give a scope different from that prescribed by Law 1335 of 2009, in view of the fact that in sanctioning matters, the description of the conduct that

 $^{^{8}\} http://www.corteconstitucional.qov.co/relatoria/2000/c-739-00.htm$

gives rise to the sanction must be precise, clear, and not give rise to doubts, it is clear for this Directorate, that it is not possible to apply Law 1335 of 2009 to the product called IQOS, since it falls outside the scope of competition prescribed by the legislator in the aforementioned normative provision and doing so could lead to the violation of the due process established in subsection 2 of article 29 of the Constitution, which provides that: "No one can be judged except in accordance with the pre-existing laws to the act that is imputed (...)".

Consequently, taking into account the above, this Office proceeds to consider completed the preliminary investigation carried out against COLTABACO S.A.S and PHILIP MORRIS COLOMBIA S.A, registered under number 17-082520, and will refrain from advancing administrative investigation against them derived from the considerations above, as there is no evidence of an alleged violation of the legal rules of consumer protection for the facts that are the subject of that preliminary inquiry, related to the alleged advertising, promotion and sponsorship of IQOS products.

Finally, this Directorate provides that folios 252 to 253, 269 to 270, 350 to 365 and 424 to 434 be broken down, to be assigned a new file. In the same way, that folios 455 to 494 of this proceeding be broken down and transferred to the proceeding with filing No. 19-87407.

Sincerely,

PAOLA ANDREA PÉREZ BANGUERA HEAD OF INVESTIGATIONS OF CONSUMER PROTECTION

Prepared by: YLAG Reviewed by: PAPB Approved by: PAPB