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Text n°27

Order n° 2016-623 of May 19, 2016, concerning transposition of Directive 2014/40/UE on the manufacture, display and sale of tobacco products and related products

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The President of the Republic,

Based on the report of the Prime Minister and the Minister of Social Affairs and Health,

In light of the Constitution, particularly its Article 38;

In light of (EC) Rule n° 1907/2006 of December 18, 2006, concerning the registration, assessment and authorization of chemical substances, as well as the restrictions applicable to such substances, and establishing a European agency for chemical products;

In light of (EC) Rule n° 1272/2008 of December 16, 2008, regarding the classification, labeling and packaging of substances and blends, amending and superseding Directives 67/548/CEE and 1999/45/CE, and amending (EC) Rule n° 1907/2006;

In light of Directive 2014/40/UE of the European Parliament and Council, of April 3, 2014, concerning the harmonization of legislative, regulatory and administrative provisions of the member States with respect to the manufacture, display and sale of tobacco products and related products, and superseding Directive 2001/37/CE;

In light of the Code of Social Action and Families, particularly its Articles L. 211 - 1 and L. 211-2;

In light of the Consumer Code, particularly its Article L. 421 - 1;

In light of the Customs Code, particularly its Article 67, part 5;

In light of the General Tax Code, particularly its Articles 572 and 575 D;

In light of the Penal Code;

In light of the Code of Public Health;

In light of the Code of Internal Security;

In light of the Labor Code;

In light of the Book of Fiscal Procedures, particularly its Article L. 80 N;

In light of Law n° 78 - 17 of January 6, 1978, as amended, relating to computer science, files and freedoms;

In light of Law n° 2016-41 of January 26, 2016, regarding the modernization of our health system, particularly its Article 216;

The Council of State having been duly consulted;

The Council of Ministers having been duly consulted,

Orders:

Article 1

Title One of Book V of the third part of the Code of Public Health is to be replaced by the following provisions:

"Title One

"TOBACCO CONTROL

"Chapter 1

"Information and prevention

"Art. L. 3511 - 1. - The Government shall set by decree the date of an annual event entitled: "No Tobacco Day."

"Art. L. 3511-2. - Protective and psychological health information is to be given out at educational institutions and to the armed forces.

"In the context of health education, a mandatory campaign to raise awareness is to be organized for primary and secondary school classes.

"Art. L. 3511-3. - Nicotine substitutes can be prescribed by:

"1° Physicians, including occupational physicians prescribing them to workers;

"2° Oral surgeons, pursuant to Article L. 4141-2;

"3° Midwives, pursuant to Article L. 4151-4;

"4° Nurses, pursuant to Article L. 4311 - 1;

"5° Masseurs - physiotherapists, pursuant to Article L. 4321 - 1.

"Chapter II

"Tobacco products

"Section 1

"General provisions

"Art. L. 3512 - 1. - All products that can be consumed and are composed, even partially, of tobacco, whether or not it is genetically modified, are considered to be tobacco products.

"Tobacco products include cigarettes, rolling tobacco, pipe tobacco, water pipe tobacco, cigars, cigarillos, chewing tobacco, snuff and tobacco for oral use.

"New tobacco products, which are products other than those mentioned in the second sub-paragraph, and that came onto the market after May 19, 2014, are also tobacco products in the sense of the first sub-paragraph.

"Art. L. 3512-2. - Tobacco and additives, as well as any other substance or any other element present in a finished tobacco product, is considered an ingredient, including the paper, filter, ink, capsules and glues.

"Art. L. 3512-3. - Tobacco products intended for use by consumers or retailers to make cigarettes is considered rolling tobacco. If a product can be used both for a water pipe and as rolling tobacco, it is considered to be rolling tobacco.

"Art. L. 3512-4. - Advertising or publicity, whether direct or indirect, for tobacco, tobacco products, and the ingredients defined in Article L. 3512-2, as well as any free distribution or sale of a tobacco product at a price lower than that authorized in accordance with Article 572 of the General Tax Code, are prohibited.

"These provisions do not apply to signs for tobacco shops, as long as such signs are in compliance with the characteristics defined by inter-ministerial administrative order.

"Nor do they apply to:

- "1° Online publications and communication services published by professional organizations of producers, manufacturers and distributors of tobacco products, restricted to their members, nor to specialized professional publications a list of which is established by administrative order signed by the Ministers of Health and Communication, nor to online communication services published for professional purposes that are only accessible to professionals engaged in the production, manufacture and distribution of tobacco products;
- "2° Publications printed and published, and online communication services made available to the public by persons established in a country not belonging to the European Union or the European Economic Area, as long as these publications and online communication services are not primarily intended for the community market.

- "Any operation of sponsorship or underwriting is prohibited when it is performed by manufacturers, importers or distributors of tobacco products, or when its purpose or effect is to engage in direct or indirect advertising or publicity for tobacco, tobacco products and the ingredients defined in Article L. 3512-2.
- "Art. L. 3512-5. Advertising or publicity on behalf of an organism, service, activity, product or an item other than tobacco, a tobacco product or an ingredient defined in Article L. 3512-2 is considered indirect advertising or publicity when, through its graphic representation, its display, the use of a brand, an advertising emblem or other distinctive sign, it calls to mind tobacco, a tobacco product or an ingredient defined in Article L. 3512-2.
- "However, these provisions are not applicable to advertising or publicity for a product other than tobacco, a tobacco product or an ingredient defined in Article L. 3512-2 that has come onto the market prior to January 1, 1990, by a company that is legally and financially separate from any company that manufactures, imports or sells tobacco, a tobacco product or an ingredient defined in Article L. 3512-2. The creation of a legal or financial link between such companies shall render this exception null.
- "Art. L. 3512-6. The re-broadcast of sports competitions containing direct or indirect advertising for the products mentioned in Article L. 3512-5, and that take place in countries where advertising for tobacco is allowed, can be undertaken by television networks.
- "Art. L. 3512-7. I. Manufacturers, importers and distributors of tobacco products, as well as companies, professional organizations or associations representing them, are to send a report each year to the Minister of Health specifying all expenses associated with influence-seeking or lobbying activities.
- "II. The following things are considered expenses associated with influence-seeking or lobbying activities:
- "1° Salaries for personnel entirely or partly engaged in influence-seeking or lobbying activities;
- "2° Expenditures for services with consulting firms on influence-seeking or lobbying activities;
- "3° Outlays in kind or in cash, of any kind whatsoever, whether direct or indirect, whose value exceeds 10 €, provided for:
- "a) Members of the Government;
- "b) Members of ministerial offices or staff of the office of the President of the Republic;
- "c) Staff of the President of the National Assembly or the President of the Senate;

- "d) Representatives in the legislature:
- "e) Persons engaged in a mission of public service whose mission, or the nature of whose duties, entails making or preparing the decisions and opinions of public officials regarding tobacco products;
- "f) Experts, whether natural or juridical persons, formally entrusted to a public figure, with a mission of advising the public figure whose job it is to make or prepare decisions and opinions of public officials regarding tobacco products.
- "III. For each company that is required to submit it, the report mentioned in paragraph I shall indicate:
- "1° The total amount of salaries mentioned in 1° of II, and the number of persons involved;
- "2° The total amount and the identity of the beneficiaries of the expenses mentioned in 2° of II;
- "3° The nature and identity of the beneficiary of each expense mentioned in 3° of II.
- "Art. L. 3512 8. It is prohibited to smoke in places assigned for shared use, particularly educational institutions, as well as in public transportation vehicles, except in areas expressly reserved for smokers.
- "Art. L. 3512 9. It is prohibited for any occupants of a vehicle to smoke in the presence of a child under the age of eighteen.
- "Section 2
- "Procedures for sale
- "Art. L. 3512 10. Article L. 3335 1 is applicable to places for the sale of processed tobacco, without impairment to acquired rights.
- "As an exception to Article L. 3335 1, and without impairment to acquired rights, a tobacco shop cannot be opened in the vicinity of an institution of public education, a private educational institution or a training institute or center for youth recreation at a distance less than a threshold to be set by the administrative order of a representative of the State in the department.
- "Art. L. 3512 11. The sale of tobacco products in automatic vending machines is prohibited.
- "Art. L. 3512 12. It is prohibited to sell the tobacco products defined in Article L. 3512 1, or the ingredients defined in Article L. 3512-2, or offer them for free in tobacco shops or any business or public place to those under the age of eighteen.
- "Any individual engaged in the issuance of such products shall require the client to prove that he is of age.
- "Art. L. 3512 13. The manufacture, sale, distribution or offering for free of products intended for oral use, except for those intended to be smoked or chewed, consisting

entirely or partially of tobacco, in the form of powder, fine particles or any combination of such forms, notably those that are offered in packets or porous packets, or in a form suggestive of an edible item, is prohibited.

"Art. L. 3512 - 14. - The sale, distribution or offering for free of packs of less than twenty cigarettes and packs of more than twenty that are not made up of a number of cigarettes that is a multiple of five, as well as those containing less than thirty grams of fine cut tobacco intended for rolling cigarettes, regardless of how they are packaged, is prohibited.

"Section 3

- "Ingredients and emissions
- "Art. L. 3512 15. I. The sale, distribution or offering for free of cigarettes whose maximum content in tar, nicotine and carbon monoxide emissions is greater than the amounts set by administrative order of the Minister of Health, is prohibited.
- "II. This administrative order shall also determine:
- "1° Methods of analysis for measuring cigarettes' tar, nicotine and carbon monoxide content;
- "2° Methods for ascertaining the accuracy of the declared content.
- "III. The measurements of emissions mentioned in I are to be verified by approved laboratories overseen by a public institution designated by administrative order. Such laboratories shall not belong to the tobacco industry, nor shall they be controlled by the latter.
- "A decree shall determine the conditions for the approval and oversight of the laboratories mentioned above.
- "Art. L. 3512 16. I. The sale, distribution or offering for free is prohibited for cigarettes and rolling tobacco:
- "1° That is flavored, having a scent or taste that is clearly identifiable before or during consumption, other than that of tobacco;
- "2° Whose filters, paper, capsules, packaging or any other component contain tobacco, nicotine or flavoring agents;
- "3° Containing any technical devices that make it possible to modify the scent or taste of tobacco products, or to intensify their combustion;
- "4° Containing vitamins or other additives fostering the impression that a tobacco product has beneficial health effects, or that the risks it poses to health have been reduced:
- "5° Containing caffeine, taurine or other additives and stimulants associated with energy and vitality;

- "6° Containing additives that confer coloring properties on smoke emissions:
- "7° Containing additives that facilitate inhalation or the absorption of nicotine;
- "8° Containing additives that, without combustion, have carcinogenic, mutagenic or toxic properties for human reproduction;
- "9° Containing additives in quantities that significantly or measurably increase their toxic effects, or the addictive effect that they give rise to, when they are consumed.
- "II. Paragraphs 4 to 6° and 8° of I apply to other tobacco products.
- "7 of I applies to other tobacco products for smoking.
- "2° and 3° of I also apply to papers and filters sold, distributed or offered separately.
- "III. I shall enter into force on May 20, 2020, for tobacco products containing a flavoring agent that is clearly identifiable, whose sales volume within the European Union as of May 20, 2016, represents 3% or more for a particular category of tobacco products.
- "Art. L. 3512 17. I. Before putting any tobacco product on the market, manufacturers and importers of tobacco products are to submit to the public agency indicated by administrative order a list by brand and type of all ingredients used in the manufacture of the tobacco products and their emissions.
- "This declaration shall include information particularly concerning the status of the ingredients with regard to (EC) Rule n° 1907/2006 of December 18, 2006, and (EC) Rule n° 1272/2008 of December 16, 2008, the toxicological data and health effects of the product, the reason for the use of the ingredients, as well as a general description of the additives used and their properties.
- "II. At the latest, eighteen months after an additive has been registered in the priority list established by the European decision mentioned in Article 6 of Directive 2014/40/ UE, manufacturers and importers are to submit in-depth studies that they have conducted on the matter.
- "III. For new tobacco products defined in the third sub-paragraph of Article L. 3512 1, a supplementary notification is to be sent six months prior to their entry onto the market. This notification shall include studies in particular concerning toxicity, addictive effects, the product's attractiveness and its market.
- "Art. L. 3512 18. Manufacturers and importers of tobacco products shall communicate to the public agency designated by administrative order internal and external studies concerning the market and preferences of groups of consumers with regard to ingredients and emissions, and summaries of studies with a view towards the release of new products. They shall annually declare to this agency the volume of their sales for the year that has elapsed, by brand and type.
- "Art. L. 3512 19. All declarations mentioned in Articles L. 3512 17 and L. 3512 18 or any amendment thereof, shall be subject to a payment by the manufacturer or importer of tobacco products, payable to the public agency mentioned in Article L. 3512 17, of a fee for the reception, storage, processing, analysis and publication of information, as well as for

verification of the measures indicated in Article L. 3512 - 16 and the studies indicated in Article L. 3512 - 17.

"The amount of these fees is to be set by decree up to a limit of 7,600 €.

"These fees are to be collected according to the procedures set forth for receipt of payments to administrative public agencies of the State.

"Section 4

"Characteristics of packaging

"Art. L. 3512-20. - Without impairment to the provisions of Article 575 D of the General Tax Code, packaging units, external wrappings and outer wrappings of cigarettes and rolling tobacco, cigarette paper and cigarette rolling papers are to be neutral and standardized.

"Art. L. 3512-21. - I. - Labeling of packaging units, any external wrapping, as well as the tobacco product itself, may not include any element or device that:

"1° Contributes to the promotion of a tobacco product, or incites its consumption by giving an erroneous impression with regard to the characteristics, health effects, risks or emissions of this product;

"2° Resembles a food or cosmetic product.

"II. - The elements and items that are prohibited on the basis of I particularly include messages, symbols, names, commercial brands, figurative or other signs.

"Art. L. 3512-22. - I. - Packaging units and external wrappings shall exhibit the following, pursuant to conditions to be set by an administrative order of the Minister of Health:

"1° For tobacco products that are for smoking:

- "a) A health warning applied twice, particularly showing information on quitting tobacco, together with a photograph;
- "b) A general warning;
- "c) An informational message. This message is to be applied twice when these products are packaged in soft boxes with a folding lid;
- "2° For smokeless tobacco products, a health warning applied twice.
- "II. Packaging units of cigarette rolling papers shall include, pursuant to conditions to be set by an administrative order of the Minister of Health, a general warning and a warning including information on quitting tobacco.

"Section 5

"Traceability

- "Art. L. 3512-23. I. Packaging units of tobacco products manufactured in France, imported by a non-member State of the European Union or coming from a member State of the European Union, are to be supplied with a unique identifier, printed or applied in an unremovable and indelible fashion. This identifier is not to be concealed or broken up, and it shall provide access to data on manufacture and the movements of such tobacco products.
- "II. Persons involved in the commerce of tobacco products, from the manufacturer to the last operator before the first retailer, are to record the arrival of all packaging units in their possession, as well as all intermediate movements and the definitive departure of the packaging units.
- "Persons taking part in the supply chain for tobacco products are to keep a complete and exact list of all operations involved.
- "III. Manufacturers of tobacco products are to provide all persons involved in the commerce for such products, from the manufacturer to the last operator before the first retailer, including importers, warehouses and shipping companies, with the necessary equipment to record tobacco products purchase, sold, stored in inventory, shipped or subject to any other handling. This equipment will make it possible to read the recorded data and to transmit it electronically to a data storage facility.
- "Art. L. 3512-24. I. Manufacturers and importers of tobacco products shall enter into a contract for storage of data accessible by the unique identifier with an independent third party, with the aim of accommodating the storage facility for the data mentioned in III of Article L. 3512-23.
- "The independent third party is to be approved by the European Commission, particularly with respect to its independence and its technical proficiency. The same shall apply to the data storage contract.
- "II. The information mentioned in I is to undergo personal data processing pursuant to the terms of Law n° 78 17 of January 6, 1978, as amended, relating to computer science, files and freedoms. It cannot be modified or deleted by any person involved in the commerce of tobacco products.
- "III. The data storage facility is to be physically located within the territory of the European Union. The European Commission shall have full access to this facility. Agents authorized by the Ministries of Health and Customs shall have full access to the components of this facility located in French territory. They shall have electronic access to the information mentioned in I, through a link to the unique identifier.
- "IV. The activities of the independent third party are to be overseen by an external auditor, appointed and paid by the manufacturer or importer, and approved by the European Commission. The external auditor shall submit to the Minister of Health, the Minister of Customs and the European Commission an annual report in which there shall appear in particular any irregularities associated with access to the data stored by the independent

third party.

"Art. L. 3512-25. - In addition to the unique identifier mentioned in Article L. 3512-23, packaging units of tobacco products manufactured or imported by a non-member State of the European Union, or coming from a member State of the European Union, shall include a security device that cannot be falsified, made up of visible and invisible elements.

"The security device is to be printed or applied in an unremovable and indelible fashion. It is not to be concealed or broken up.

"Art. L. 3512-26. - A decree of the Council of State shall determine the conditions for the implementation of this Chapter, particularly:

"1° The report template mentioned in Article L. 3512-7;

"2° The terms for the implementation of Article L. 3512 - 16;

"3° The content of the declarations mentioned in Articles L. 3512 - 17 and L. 3512 - 18, and their procedures for transmission and updating, the nature of the information that is made public and the terms of its publication;

"4° The conditions for neutrality and standardization of packages of tobacco products as set forth in Article L. 3512-20, particularly with regard to form, size, texture and color, and the procedures for printing of brand names and commercial titles on these elements;

"5° The main categories of elements or devices contributing to the promotion of a tobacco product which are prohibited as per 1° of Article L. 3512-21;

"6° Following the opinion of the Commission nationale de l'informatique et des liberties ('National Commission of Computer Science and Freedoms'), the procedures for implementation of traceability as set forth by Articles L. 3512-23 to L. 3512-25.

"Chapter III

"Vaping products

"Section 1

"Common provisions

"Art. L. 3513-1. - The following are considered to be electronic cigarette ("Vaping") products:

"1° Electronic devices for vaping, that is to say, products, or any component of such products, including cartridges, reservoirs and devices without a cartridge or reservoir, that can be used with a mouthpiece, for consumption of vapor, in some cases containing nicotine. Electronic vaping devices can be disposable or refillable using a refill flask and a reservoir, or with single-use cartridges;

"2° Refill flasks, that is, receptacles holding a liquid, in some cases containing nicotine, which can be used to refill an electronic vaping device.

- "Art. L. 3513-2. Products that are medications or medical devices in the sense of Articles L. 5111 1 and L. 5211 1 do not constitute vaping products.
- "Art. L. 3513-3. Additives as well as any other substance or element present in a vaping product are considered ingredients.
- "Art. L. 3513-4. Advertising or publicity for vaping products, whether direct or indirect, is prohibited.
- "These provisions do not apply:
- "1° To publications and online communication services published by professional organizations of producers, manufacturers and distributors of vaping products that are restricted to their members, nor to specialized professional publications, a list of which is to be drawn up by a ministerial administrative order signed by the Ministers of Health and Communication; nor to online communication services published for professional purposes that are only accessible to professionals engaged in the production, manufacture and distribution of vaping products;
- "2° To printed and published publications and online communication services made available to the public by persons established in a country not belonging to the European Union or the European Economic Area, when such publications and online communication services are not primarily intended for the community market;
- "3° To small posters about vaping products, posted inside establishments that sell them, and are not visible from outside.
- "All sponsorship or underwriting operations are prohibited if they have the purpose or effect of direct or indirect advertising or publicity for vaping products.
- "Art. L. 3513-5. It is prohibited to sell or offer vaping products free of charge in tobacco shops, or any other stores or public places, to minors under the age of eighteen.
- "Any individual engaged in the issuance of such products shall require the client to prove that he is of age.
- "Art. L. 3513-6. It is prohibited to vape in the following places:
- "1° Educational institutions and establishments intended for the reception, training and accommodation of minors;
- "2° Enclosed public transportation vehicles:
- "3° Enclosed and covered work places subject to shared use.
- "Section 2
- "Provisions specific to vaping products containing nicotine

"Sub-section 1

"Ingredients and emissions

"Art. L. 3513-7. - Disposable electronic vaping devices, refill flasks and single-use cartridges containing nicotine shall only contain ingredients of high purity, except for unavoidable traces from the manufacturing process.

"The sale, distribution or offering for free of disposable electronic vaping devices, refill flasks and single-use cartridges containing nicotine which include the following additives are prohibited:

- "1° Additives creating an impression that the product has beneficial health effects, or that the risks it poses to health have been reduced;
- "2° Additives and stimulants associated with energy and vitality;
- "3° Additives that confer colored properties on emissions;
- "4° Additives that facilitate the inhalation or absorption of nicotine;
- "5° Additives that, without combustion, have carcinogenic, mutagenic or toxic properties for human reproduction.
- "Art. L. 3513-8. For vaping products containing nicotine, apart from nicotine, only ingredients are to be used that, whether heated or not, do not pose any risk to human health.

"Maximum nicotine content levels for these products are to be set by administrative order of the Minister of Health.

"Under normal use conditions, electronic vaping devices shall diffuse nicotine at a constant rate.

- "Art. L. 3513-9. Vaping products containing nicotine shall include a safety device whose characteristics are to be determined by administrative order of the Minister of Health.
- "Art. L. 3513-10. Six months prior to placement on the market of vaping products containing nicotine, manufacturers and importers are to submit to a public agency designated by administrative order, a file of notification by brand and product type.
- "This file shall contain information particularly on the parties responsible for such placement on the market, on the composition, emissions, toxicological data on ingredients and emissions, components and manufacturing process of the product.
- "Art. L. 3513-11. Manufacturers and importers of vaping products containing nicotine shall annually declare sales data to the the public agency mentioned in Article L. 3513-10 for the year that has elapsed by brand and type, as well as summaries of the market studies that they have carried out.

"Art. L. 3513-12. - All of the notification mentioned in Article L. 3513-10 shall give rise to a payment to be made to the public agency mentioned in that Article, of a fee for the reception, storage, processing, and analysis of information, for which the amount is to be set by decree, up to a limit of 7,600 €.

"These fees are to be collected according to what is set forth regarding the receipt of payments made to administrative public agencies of the State.

"Art. L. 3513-13. - Manufacturers, importers and distributors of vaping products containing nicotine shall put in place and keep up to date a system for the collection of information on all undesirable effects on human health ascribed to these products.

"If any of the economic operators believes, or has reason to think that the products that are in his possession and are intended to be placed on the market or have been placed on the market are not safe, are not of good quality or are not in compliance with the terms of this Chapter, such economic operator shall immediately take the necessary corrective measures to bring the product in question into compliance, to withdraw it or recall it, as appropriate.

"In these cases, the economic operator shall immediately inform the public agency mentioned in Article L. 3513-10, specifying in particular the risks to human health and safety, any corrective measures taken, as well as the results of such corrective measures.

"Additional information can be requested of economic operators by the public agency mentioned in Article L. 3513-10, for example regarding aspects bearing on safety and quality, or on any possible undesirable effects of such products.

"Art. L. 3513-14. - If the public agency mentioned in Article L. 3513-10 observes or has reasonable grounds to believe that a vaping product containing nicotine, or that a particular kind of product could pose a serious risk to human health, he shall immediately inform the Ministry of Health, proposing to it the appropriate interim measures.

"Sub-section 2

"Presentation of product

"Art. L. 3513-15. - An administrative order of the Minister of Health shall define the maximum volume for the reservoir of disposable electronic vaping devices and single-use cartridges and for refill flasks containing nicotine.

"Art. L. 3513-16. - All packaging units and external wrapping for vaping products containing nicotine shall state the following:

"1° The complete composition of the liquid containing nicotine;

"2° The average nicotine content and the quantity administered per dose;

"3° The lot number;

- "4° A recommendation to the effect that the product must be kept out of the reach of children;
- "5° A health warning applied twice.
- "An administrative order of the Minister of Health shall set the characteristics and procedures for the printing of these mandatory statements, the methods of analysis allowing for measurement of the nicotine content and the methods for ascertaining the accuracy of the statements appearing on packaging units.
- "Art. L. 3513-17. All packaging units of vaping products containing nicotine shall include a notice whose characteristics are to be defined by administrative order of the Minister of Health.
- "Art. L. 3513-18. I. Labeling of packaging units, all external wrappings, as well as the vaping product containing nicotine itself may not include any element or device that:
- "1° Contributes to the promotion of vaping products, or incites their consumption by giving an erroneous impression regarding the characteristics, health effects, risks or emissions of the product;
- "2° Suggests that the product is less harmful than others, or claims to reduce the effect of certain harmful components in the smoke, or that it presents invigorating, energizing, curative, rejuvenating, natural or biological properties, or has beneficial effects on health or one's lifestyle;
- "3° Resembles a food or cosmetic product:
- "4° Suggests that the product is more easily biodegradable, or provides other advantages for the environment;
- "5° Suggests an economic advantage through printed bonuses, rebate offers, free samples, "two for the price of one" promotions or other similar offers.
- "II. Elements and devices that are prohibited on the basis of I, particularly those including messages, symbols, names, commercial brands, figurative or other signs.
- "Art. L. 3513-19. In the absence of provisions to the contrary, a decree of the Council of State shall determine the terms for the implementation of this Chapter, particularly those concerning Articles L. 3513-6 and L. 3513-7, as well as the content of the notification and declaration mentioned in Articles L. 3513-10 and L. 3513-11, their procedures for transmission and updating, the nature of the information that is made public and the terms set forth for such purpose.

"Chapter IV

- "Smoking products derived from plants other than tobacco
- "Art. L. 3514 1. Products derived from vegetables, aromatic plants or fruits, not containing tobacco and that can be consumed through a process of combustion are considered to be Smoking products derived from plants other than tobacco.

- "Art. L. 3514-2. Additives as well as any other substance or element present in a smoking product derived from plants other than tobacco are considered ingredients, as well as any other substance or other element present in a smoking product derived from plants other than tobacco, including the paper, filter, ink, capsules and glues.
- "Art. L. 3514-3. I. Labeling of packaging units and all external wrapping, as well as the smoking product derived from plants other than tobacco itself, may not include any element or device that:
- "1° Contributes to the promotion of a tobacco product, or incites its consumption by giving an erroneous impression with regard to the characteristics, health effects, risks or emissions of the product; labels are not to include any information on the nicotine, tar or carbon monoxide content of the product;
- "2° Suggests that the product is less harmful than others, or claims to reduce the effect of certain harmful components in the smoke, or that it presents invigorating, energizing, curative, rejuvenating, natural or biological properties, or has beneficial effects on health or one's lifestyle;
- "3° States that the product is free of additives or flavoring agents;
- "4° Resembles a food or cosmetic product;
- "II. The elements and devices that are prohibited on the basis of I include in particular messages, symbols, names, commercial brands, figurative or other signs.
- "Art. L. 3514-4. All packaging units and external wrappings for smoking products derived from plants other than tobacco shall include a health warning pursuant to conditions to be set by an administrative order of the Minister of Health.
- "Art. L. 3514-5. Before placing on the market any smoking product derived from plants other than tobacco, manufacturers and importers of such products shall submit a declaration of the ingredients used by brand and product type to the public agency designated by administrative order.
- "Art. L. 3514-6. A decree of the Council of State shall determine the terms for the implementation of this Chapter, particularly the content of the declaration, the procedures for transmission and updating, the nature of the information to be made public and the procedures according to which they are to be done.

"Chapter V

"Penal provisions

"Section 1

"Enforcement

"Art. L. 3515 - 1. - The officers mentioned in Article L. 1312 - 1 of this code, in Articles L. 8112 - 1, L. 8112-3 and L. 8112-5 of the Labor Code, shall see to compliance with Articles L. 3512 - 8, L. 3512 - 12, L. 3513-5 and L. 3513-6 of this code as well as the regulations

adopted for its implementation, and shall proceed to investigate and ascertain violations of these provisions.

"To such end, for each one insofar as it concerns him, these officers shall be endowed with the prerogatives that are ascribed to them by Articles L. 1312 - 1 of this code, L. 8113-1 to L. 8113-5 and L. 8113-7 of the Labor Code, and by the regulatory texts adopted for their implementation.

"To ascertain a violation of Articles L. 3512 - 12 and L. 3513-5, these officers may require the client to establish proof that he is of age, by presenting any official document with photo ID.

"Art. L. 3515-2. - Municipal police officers, rural policemen, security officers in Paris as well as officers of the city of Paris entrusted with the police duties mentioned, respectively, in Articles L. 511 - 1, L. 521 - 1, L. 523-1 and L. 531 - 1 of the Code of Internal Security, can establish through written reports infractions of Articles L. 3512 - 8, L. 3512 - 12, L. 3513-5 and L. 3513-6 of this Code and of the regulations adopted for their implementation, when they have been committed in communal territory, in the territory of the city of Paris, or in the territory that they are sworn to protect, and as long as they do not in turn require criminal investigations.

"To ascertain violations of Articles L. 3512 - 12 and L. 3513-5, these officers may require that the client prove that he is of age, by presenting any official document with a photograph.

"Section 2

"Sanctions and penal liability

"Art. L. 3515-3. - I. - The following infractions are punishable by a fine of 100,000 euros:

- "1° Any advertising or publicity, whether direct or indirect, for tobacco, a tobacco product or the ingredients defined in Article L. 3512 1, in disregard of the prohibition set forth in Article L. 3512-4;
- "2° The act of re-broadcasting a sports competition containing direct or indirect advertising for tobacco and taking place in a country where advertising for tobacco is prohibited, as well as the re-broadcast, by a means other than a television network, of a sports competition containing direct or indirect advertising for tobacco, and taking place in a country where advertising for tobacco is allowed, in disregard of the provisions of Article L. 3512-6;
- "3° The act of selling, distributing or offering for free packs of less than twenty cigarettes, packs of more than twenty cigarettes that are not made up of a number of cigarettes that is a multiple of five, or containing less than thirty grams of fine cut tobaccos intended for rolling cigarettes, regardless of their packaging;
- "4° The act of selling, distributing or offering for free cigarettes whose content in tar, nicotine and carbon monoxide emissions exceeds the maximum content levels set by the terms of paragraph I of Article L. 3512-15;
- "5° The act of selling, distributing or offering for free cigarettes or rolling tobacco:

- "a) That are flavored cigarettes, having a scent or taste that is clearly identifiable before or during consumption, other than that of tobacco;
- "b) Whose filters, paper, capsules, packaging or any other component contain tobacco, nicotine or flavoring agents;
- "c) Containing any technical device making it possible to modify the scent or taste of tobacco products, or the intensity of their combustion;
- "d) Containing vitamins or other additives fostering the impression that a tobacco product has beneficial health effects, or that the risks that it poses to health have been reduced;
- "e) Containing caffeine, taurine or other additives and stimulants associated with energy and vitality;
- "f) Containing additives that confer colorizing properties on smoke emissions;
- "g) Containing additives that facilitate the inhalation or absorption of nicotine;
- "h) Containing additives that, without combustion, have carcinogenic, mutagenic or toxic properties for human reproduction;
- "i) Containing additives in quantities that significantly or measurably increase their toxic effects, or the addictive effect that they give rise to, when they are consumed.
- "6° The act of selling, distributing or offering for free paper and filters:
- "a) Containing tobacco, nicotine or flavoring agents;
- "b) Containing any technical device making it possible to modify their scent or taste, or the intensity of the cigarette's combustion;
- "7° The act of selling, distributing or offering for free cigarettes, rolling tobacco, cigarette paper and cigarette rolling papers, in disregard of the provisions of Article L. 3512-20, which imposes neutrality and standardization of packaging units, outer wrappings and external wrappings;
- "8° The act of using on the labeling of packaging units, on any external wrapping, or on tobacco products themselves, a message, symbol, brand, commercial title, figurative sign or any other element or device that:
- "a) Contributes to the promotion of a tobacco product;
- "b) Resembles a food or cosmetic product;
- "9° The act of using a brand or a title on the labeling of packaging units, on any external wrapping, or on tobacco products themselves, in disregard of the provisions of Article L. 3512-21 of the Code of Public Health;

- "10° The act of selling, distributing or offering for free tobacco products or cigarette rolling papers in packaging units and external wrappings, in disregard of the requirements stated with regard to the health warnings set forth in Article L. 3512-22;
- "11° Any advertising or publicity for vaping products, whether direct or indirect, in disregard of the prohibition set forth in Article L. 3513-4;
- "12° The act of selling, distributing or offering for free disposable electronic vaping devices, refill flasks or single-use cartridges containing nicotine that include the following additives:
- "a) Additives creating the impression that the product has beneficial health effects, or that the risks that it poses to health have been reduced;
- "b) Additives and stimulants associated with energy and vitality;
- "c) Additives that confer colorizing properties on emissions;
- "d) Additives that facilitate inhalation or the absorption of nicotine;
- "e) Additives that, without combustion, have carcinogenic, mutagenic or toxic properties for human reproduction;
- "13° The act of selling, distributing or offering for free vaping products whose content in nicotine exceeds the maximum content levels set in the conditions of the second sub-paragraph of Article L. 3513-8;
- "14° The act of selling, distributing or offering for free vaping products containing nicotine without a safety device, or whose safety device disregards the provisions of Article L. 3513-9;
- "15° The act of selling, distributing or offering for free a disposable electronic vaping device whose reservoir exceeds the maximum volume set in the conditions of Article L. 3513-15;
- "16° The act of selling, distributing or offering for free single-use cartridges whose reservoir exceeds the maximum volume set in the conditions of Article L. 3513-15;
- "17° The act of selling, distributing or offering for free a refill flask containing nicotine whose maximum volume disregards the provisions of Article L. 3513-15;
- "18° The act of selling, distributing or offering for free a vaping product containing nicotine whose packaging unit or external packaging does not mention one or several of the following elements:
- "a) The complete composition of the liquid containing nicotine;
- "b) The average nicotine content and the quantity administered per dose;
- "c) The lot number;

- "d) A recommendation to the effect that the product must be kept out of the reach of children;
- "e) A health warning applied twice;
- "19° The act of selling, distributing or offering for free a vaping product containing nicotine whose packaging unit does not include a notice, in disregard of the provisions of Article L. 3513-17:
- "20° The act of using, on packaging units or on any external wrapping of vaping products containing nicotine, a message, symbol, brand, commercial title, figurative sign or any other element or device that:
- "a) Contributes to the promotion of vaping products, or incites their consumption by giving an erroneous impression with regard to the characteristics, health effects, risks or emissions of the product;
- "b) Suggests that the product is less harmful than another, or claims to reduce the effect of certain harmful components in the smoke, or that it presents invigorating, energizing, curative, rejuvenating, natural or biological properties, or has beneficial effects on health or one's lifestyle;
- "c) Resembles a food or cosmetic product;
- "d) Suggests that the product is more easily biodegradable, or presents other advantages for the environment;
- "e) Suggests an economic advantage through printed bonuses, rebate offers, free samples, "two for the price of one" promotions or other similar offers;
- "21° The act of using on packaging units or any external wrapping of smoking products derived from plants other than tobacco, a message, symbol, brand, commercial title, figurative sign or any other element or device that:
- "a) Contributes to the promotion of the product, or incites its consumption by giving an erroneous impression with regard to the characteristics, health effects, risks or emissions of the product; whose labels do not include any information on the product's nicotine, tar or carbon monoxide content;
- "b) Suggests that a product is less harmful than another, or claims to reduce the effect of certain harmful components in the smoke, or that it presents invigorating, energizing, curative, rejuvenating, natural or biological properties, or has beneficial effects on health or one's lifestyle;
- "c) Indicates that the product is free of additives or flavoring agents:
- "d) Resembles a food or cosmetic product;

- "22° The act of selling, distributing or offering for free a smoking product derived from plants other than tobacco whose packaging unit and external packaging disregard the provisions of Article L. 3514-4 on health warnings.
- "II. The penal infractions mentioned in I are subject to the supplementary punishment of confiscation of the thing that served or was intended for the commission of the infraction, or of the thing that is the product thereof, pursuant to Article 131-21 of the Penal Code.
- "III. Repeat offenses are punishable by a fine of 200,000 €. In cases of repeat offenses, the court may, moreover, impose a prohibition of the sale of the products that were involved in the illegal operation for a period less than or equal to five years.
- "If there are grounds, the court shall order the suppression, removal or confiscation of the prohibited advertising at the expense of the offenders.
- "Cessation of advertising can be ordered either at the requisition of the Public Prosecutor, or at the discretion of the investigating magistrate or court conducting the prosecution. The measure thus taken is executory and not subject to any appeal. Release can be given by the jurisdiction that ordered it, or that is in charge of the case. The measure shall cease to have effect in the event of a finding of lack of grounds or dismissal.
- "Decisions ruling on petitions for release can be subject to an appeal before the investigating court, or before the court of appeals, depending on whether they were handed down by an investigating magistrate or by the court conducting the prosecution.
- "The investigating court, or the court of appeals, shall issue a ruling within a period of ten days counting from the receipt of the items of evidence.
- "Art. L. 3515-4. The following things are punishable by a fine of 45,000 euros:
- "1° The act of a manufacturer or importer of a tobacco product that places on the market a tobacco product without having submitted the declaration defined in Article L. 3512 17;
- "2° The act of a manufacturer or importer of a tobacco product failing to send a market study, in disregard of the provisions of Article L. 3512 18;
- "3° The act of importing tobacco products, with a view to their sale, distribution or offering free of charge, that are manufactured in a non-member State of the European Union or coming from a member State of the European Union whose packaging unit does not exhibit the unique identifier, in disregard of the provisions of Article L. 3512-23;
- "4° The act of importing tobacco products, with a view to their sale, distribution or offering free of charge, that are manufactured in a non-member State of the European Union or coming from a member State of the European Union whose packaging unit does not include the unfalsifiable security device, in disregard of the provisions of Article L. 3512-25;
- "5° Any modification or alteration by any person concerned in the commerce of tobacco products, from the manufacturer to the last operator before the first retailer, of the information contained in the processing of data managed by the independent third party indicated in Article L. 3512-24:

- "6° The act of a manufacturer or importer that places on the market a vaping product containing nicotine without having undertaken to give notification pursuant to the conditions and deadlines defined in Article L. 3513-10:
- "7° The act of a manufacturer or importer of a vaping product failing to send the annual declaration for the year that has elapsed, in disregard of the provisions of Article L. 3513-11:
- "8° The act of a manufacturer, distributor or importer of a vaping product failing to put in place or keep up to date the system for collecting information mentioned in Article L. 3513-13, on all the undesirable effects on human health ascribed to these products;
- "9° The act of a manufacturer, distributor or importer of a vaping product failing to immediately inform the public agency mentioned in Article L. 3513-10 of risks to human health and safety posed by a vaping product that it is placing on the market or selling, in violation of the provisions of the third sub-paragraph of Article L. 3513-13;
- "10° The act of a manufacturer, distributor or importer of a vaping product failing to send to the public agency mentioned in Article L. 3513-10 any additional information that it requires of it, pursuant to Article L. 3513-13;
- "11° The act of a manufacturer or importer of a smoking product derived from plants other than tobacco that places such a product on the market in disregard of the requirement to declare the ingredients used, as defined in Article L. 3514-5.
- "Art. L. 3515-5. The act of manufacturers, importers and distributors of tobacco products, as well as companies, professional organizations or associations representing them that fail to send to the Minister of Health the annual report indicated in Article L. 3512-7 or knowingly fail to make public the expenses that should be included therein, in application of the same Article, is punishable by a fine of 45,000 €.
- "Art. L. 3515-6. Juridical persons found criminally liable of the infractions defined in Articles L. 3515-3 and L. 3515-4, in addition to the fine whose maximum rate is to be defined in accordance with the terms set forth in Article 131-38 of the Penal Code, pursuant to the conditions set forth in Article 121-2 of the Penal Code, are punishable by the following penalties:
- "1° The suppression, removal or confiscation of the prohibited advertising, at the expense of the offenders;
- "2° In cases of repeat offenses, prohibition of sale of the products that were involved in the illegal operation, for a period less than or equal to five years.
- "In the event of prosecution, cessation of the advertisement can be ordered either at the requisition of the Public Prosecutor, or at the discretion of the investigating magistrate or court conducting the prosecution. The measure thus taken is executory and not subject to any appeal. Release can be given by the jurisdiction that ordered it, or that is in charge of the case. The measure shall cease to have effect in the event of a finding of lack of grounds or dismissal.
- "Decisions ruling on petitions for release can be subject to an appeal before the

investigating court, or before the court of appeals, depending on whether they were handed down by an investigating magistrate or by the court conducting the prosecution.

"Section 3

"Civil parties

"Art. L. 3515-7. - Associations whose statutory purpose involves TOBACCO CONTROL, that have been regularly established for at least five years at the date of the facts, can exercise the rights recognized for parties to civil actions in response to infractions of the provisions of this Title.

"The consumer associations mentioned in Article L. 421 - 1 of the Consumer Code, as well as the family associations mentioned in Articles L. 211 - 1 and L. 211-2 of the Code of Social Action and Families, can exercise the same rights."

Article 2

The first sub-paragraph of Article 572 of the General Tax Code is to be completed by the following sentence: "This administrative order shall mention the brand and commercial title of tobacco products on the condition that the latter respect the provisions of Article L. 3512-21 of the Code of Public Health."

Article 3

Article 569 of the General Tax Code is hereby rescinded.

Article 4

Article 67, part 5, of the Customs Code, the words: "in Article 569 of the General Tax Code" are to be replaced by the words: "in Article L. 3512-24 of the Code of Public Health."

Article 5

Article L. 80 N of the Book of Fiscal Procedures is to be amended as follows:

1° In the first sub-paragraph, the words: "in Article 569 of the same code, through the unique, securitized and indelible brand identifier, mentioned in this same Article," are to be replaced by the words: "in Article L. 3512-24 of the Code of Public Health";

2° In the second sub-paragraph, the words: "in the first sub-paragraph of the aforesaid Article 569," are to be replaced by the words: "in Article L. 3512-24 of the Code of Public Health."

Article 6

I. - The notification file mentioned in Articles L. 3512 - 17 and L. 3513-10 of the Code of

Public Health is to be sent no later than November 20, 2016, for products sold before May 20, 2016.

All first annual declarations mentioned in Article L. 3512 - 18 of the Code of Public Health are to include data as of January 1, 2015.

II. - Except for cigars, products not in compliance with the provisions of this Order can be made available for consumption up until November 20, 2016, and sold until January 1, 2017.

For cigars, products not in compliance with the provisions of this Order can be sold up until May 20, 2017.

III. - The provisions mentioned in Articles L. 3512-23 to L. 3512-25 are applicable as of May 20, 2019, to cigarettes and rolling tobacco, and as of May 20, 2024, to other tobacco products.

Article 7

The Prime Minister, the Minister of Finance and Public Accounts, the Minister of Social Affairs and Health, and the Attorney General, Minister of Justice, are responsible, each insofar as it concerns them, for the implementation of this Order, which is to be published in the *Journal official de la République française* ('Official Journal of the French Republic').

Done on May 19, 2016.

François Hollande
By the President of the Republic:

The Prime Minister, Manuel Valls

The Minister of Social Affairs and Health, Marisol Touraine

The Minister of Finance and Public Accounts, Michel Sapin

The Attorney General, Minister of Justice, Jean - Jacques Urvoas