

MINISTRY OF HEALTH

Resolution 4105/2023

RESOL-2023-4105-APN-MS

City of Buenos Aires, 06/12/2023

IN VIEW OF File No. EX-2023-59010380-APN-DGDYD#JGM, and

WHEREAS:

That in the present proceedings there is an administrative claim filed by MASSALIN PARTICULARES S.R.L., hereinafter the claimant, against the Resolution of this Portfolio of Health No. RESOL-2023-565-APN-MS dated March 23, 2023.

That the aforementioned Resolution No. 565/2023 prohibited the importation, distribution, commercialization, advertising and any form of promotion and sponsorship throughout the Argentine territory of electronic systems or devices intended to inhale tobacco vapors or aerosols, commonly known as "Tobacco Heating Products", extending such prohibition to any type of accessory intended for the operation of such systems or devices, as well as tobacco cartridges and sticks to be heated in such systems (conf. Art. 1°).

That by Article 2° of the same regulation it was provided that violations to the measure will be treated in accordance with the provisions of the Resolution of this Ministry No. 425/2014, as amended by Resolution No. 83/2019 of the former Secretariat of Government of Health, without prejudice to the penalties that may apply by application of other regulations such as the Customs Code.

That the claimant frames her petition under Article 24, paragraph a) of the Administrative Procedures Law No. 19,549.

In view of the foregoing, it is clear that what is sought is the direct challenge of the aforementioned Resolution, as an administrative act of general scope.

That, by virtue of the above, it can be concluded that MASSALIN PARTICULARES S.R.L. has standing under the terms of article 73 of the Annex to Decree No. 1759/72, which regulates the National Law of Administrative Procedures No. 19.549, since it is strictly related to the tobacco industry, and therefore it is inferred that it may be affected "in a certain or imminent manner in its subjective rights" (conf. art. 24, sub. a, LPA).

That the claimant complains, among other issues, for considering that the MINISTRY OF HEALTH exceeded its powers and acted outside the framework and the object of regulation established by Law No. 26,687.

That, in turn, it considers that the resolution under appeal illegitimately and arbitrarily restricts the importation, distribution and commercialization of heated tobacco products, far beyond the meaning and scope of the legal framework of Law No. 26,687.

That it also noted that, in the recitals of the Resolution under attack, a very vague reference is made to the independent scientific evidence available on PTCs as sufficient cause and material for the Ministry to evaluate a potential health risk, and that the challenged Resolution establishes a prohibition above the limits and objectives of the framework law, which implies the exercise of powers not foreseen in the Law, which determine its non-compliance and a clear regulatory excess, which make the challenged general acts null and void due to lack of competence (art. 7 inc. a) LPA), and at the same time it implies the exercise of legislative powers by the Executive Branch, all of which is prohibited by article 99, incs. 20 and 30 of the LPA.

Finally, it argued that the challenged regulation is absolutely and irrevocably null and void, since it is vitiated by incompetence, since it implies the incompetent and overreaching exercise by the Executive Branch and that the right to economic freedom is violated.

That according to the claims made by the claimant, the technical report prepared by the NATIONAL TOBACCO CONTROL PROGRAM, which operates within the orbit of the NATIONAL DIRECTORATE OF INTEGRAL ADDRESS OF NON TRANSMISSIBLE DISEASES (IF-2023-87517208-APN-DNAIENT#MS), in which it explained that Resolution No. 565/2013 provides for the prohibition of the marketing and importation of PTCs, is of vital importance.

It also indicated that the measure adopted by this Ministry is aimed at protecting the health of the population of our country, therefore, the measure implemented does not generate any obstacle with the primary tobacco products destined for export, or to the eventual local production of PTC for export.

That it argued that PTCs are promoted to be used as a replacement for conventional cigarettes, especially in places where smoking is prohibited, arguing that they are devoid of the deleterious effects of tobacco combustion products.

That he stated that, according to independent research cited in the report, PTCs produce aerosols with nicotine and other chemical substances such as acetaldehyde, acrolein and formaldehyde, which are harmful to health, and as detailed in the scientific evidence referenced in the technical report, PTCs contain substances that are harmful to health, These are harmful to health and, as detailed in the scientific evidence referenced in the technical report on the potentials identified, PTCs contain substances that are found at lower and higher levels than traditional cigarettes, and even new chemicals whose health impact is still unknown.

He emphasized that smoking is the leading cause of preventable death in the world and kills more than 8 million people each year.

That, within this framework, it indicated that there is no basis from the public health point of view to allow the introduction and marketing of a new product when it is already known to be harmful to health.

That it stated that the technical report that provided sufficient motivation for the issuance of Resolution No. 565/2023 contemplated all the technical-scientific issues that provided the basis for the decision adopted, as established in the Law of Administrative Procedures to that effect and that therefore there is no basis from the point of view of public health to allow the introduction and marketing of a new product that is harmful to health.

That, with respect to the above report, both the NATIONAL DIRECTORATE OF INTEGRAL ADDRESS OF NON-TRANSMISSIBLE DISEASES and the SUBSECRETARIATY OF HEALTH STRATEGIES have expressed their conformity in the present proceedings, as well as the SECRETARIAT OF ACCESS TO HEALTH.

That having determined the technical issues, as regards the legal framework, it should first be pointed out that by means of the Law of Ministries No. 22,520, it is established that the MINISTRY OF HEALTH is responsible for assisting the President of the Nation and the Chief of the Cabinet of Ministers, within its competences, in all matters related to the health of the population and the promotion of healthy behaviors in the community (Section 23) and, in particular: to intervene with preventive criteria in the reduction of morbidity due to toxins and chemical risks in all stages of the life cycle (inc. 31); and to understand in the elaboration of plans destined to the prevention and detection of endemic diseases and non-communicable diseases (inc. 34).

Furthermore, Law No. 26,687 regulates the advertising, promotion and consumption of tobacco products for the purpose of prevention and assistance to the population in the face of the damage caused by smoking (Section 1).

That the aforementioned Law has among its objectives: to reduce the consumption of tobacco products; to minimize the exposure of people to the harmful effects of smoke from tobacco products; to reduce the health, social and environmental damage caused by smoking; to prevent smoking initiation, especially among children and adolescents; and to make present and future generations aware of the consequences produced by the consumption of tobacco products and by the exposure to smoke from tobacco products (art. 2°).

That, in line with the above considerations, it is highlighted that Decree No. 602/2013, regulating Law No. 26,687, in its Article 3° establishes: "Products manufactured with tobacco shall be considered those included in the definition made in subsection b) of section 4° of the law being regulated. The following shall be considered products that may be identified with products manufactured with tobacco: a) Smoking products that are not manufactured with tobacco, such as electronic cigarettes, cigars or cigarettes of other components, etc. b) Elements or accessories for smoking: such as cigarette mouthpieces, water pipes or hookahs, electronic smoking devices and their accessories, cigarette cases, ashtrays, etc.".

That, likewise, the aforementioned regulation determines that the measurement of the toxicity of tobacco products, their ingredients and emissions shall be carried out according to scientific criteria and methods approved by the World Health Organization or those to be established by the MINISTRY OF HEALTH in the future, based on international standards (section 16, paragraph c of the Annex to the Decree).

That, in turn, this Portfolio of Health is empowered to issue complementary or interpretative rules aimed at ensuring compliance with the Law being regulated (art. 27 of the Annex to the Decree).

It should be emphasized that Law No. 25,675 (General Environmental Law) establishes that when there is a danger of serious or irreversible damage, the absence of scientific information or certainty shall not be used as a reason to postpone the adoption of cost-effective measures to prevent the degradation of the environment or, in this case, public health.

That the aforementioned precautionary principle has its population and ecological analogy in one of the foundations of medical ethics -the principle of non-maleficence, *primum non nocere*- and contains

many of the attributes of good practice in public health, such as primary prevention and the recognition that unforeseen and undesirable consequences of human actions are not infrequent.

Therefore, when there is no certainty but there are indications of possible harmful effects, actions must be taken in advance (precautionary measures) to avoid potential damage.

That, in line with the above, the "precautionary principle" was applicable to the effect that the sanitary authority favored the issuance of the measure under attack, by virtue of the exercise of reasonableness convictions supported by scientific data (in the absence of certainties due to the novelty of the product), and as a result of the use of the interpretative technique of analogy.

That on this basis, it is worth recalling what was said by the NATIONAL TOBACCO CONTROL PROGRAM in the aforementioned report, since in one of its sections it stated "On the other hand, and no less important, evidence sustains that novel products such as PTCs and similar products are especially attractive to children and adolescents, and their introduction in the market has the potential to lead to tobacco initiation in non-smoking youth and adults, threatening the achievements already obtained in tobacco control through previously implemented public policies".

That in line with the above and in relation to the use of such principle in the present health situation, and as a result of the application of the interpretative technique of analogy, it should be noted that the Office of the Treasury of the Nation has stated in its opinions that: "In the absence of precepts that specifically contemplate a given situation, it is lawful to refer to provisions of analogous laws or regulations even if they are not directly applicable in that area" (conf. Dict. 195:34; 206:203; 227:108).

That, in line with the above, it has been stated that the right to health is closely related to the right to life and the principle of personal autonomy, recognized by the National Constitution (cf. doctrine arising from Judgments: 323:1339; 323:3229; 324:3569; 326:4931; among others).

That in this order of reasoning, it should be emphasized that our National Constitution, with the reform of 1994, incorporated in its article 75, paragraph 22, numerous instruments of international law that recognize the right of the human being to health, such as article 25 of the Universal Declaration of Human Rights; Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR); Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination; Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women; and Article 24 of the Convention on the Rights of the Child.

That, within the framework of the International Covenant on Economic, Social and Cultural Rights (ICESCR), in 1985 a "Committee on Economic, Social and Cultural Rights" was created, which is the body in charge of monitoring the aforementioned Covenant, which in general is considered the fundamental instrument for the protection of the right to health.

In this regard, it should be noted that the Committee is the body to which the States submit their periodic reports on compliance with their obligations under the ICESCR.

That the recognition of Economic, Social and Cultural Rights by the States does not correspond to simple acts of good intentions, but to obligations that derive directly from international human rights treaties. In other words, if these rights are not guaranteed, human rights are neither protected nor respected.

That, in line with the above, the principle of non-regression of rights, which is included in Article 2.1. of the ICESCR, correlative to the principle of progressiveness, which entails the prohibition of adopting policies and measures that worsen the situation of economic, social and cultural rights, such as the right to health, stands out.

That the principle of non-regression should be understood as a limit to the decisions of governmental bodies and, in turn, as a guarantee in favor of the individual insofar as it protects the content of the rights he/she enjoys.

That, in this sense, it implies an obligation of the State to refrain from adopting deliberately regressive measures, based on the principles of legal certainty and the prohibition of arbitrariness.

That thus, unless it is a justified regression, States Parties must improve conditions over time without any regression whatsoever.

That, in particular, with regard to the right to health, there is a strong presumption that regressive measures adopted in relation to this right are not permissible. Thus, the failure to adopt the necessary measures to adequately protect the right to health of the population with respect to the actions of third parties implies a violation of the obligation to protect.

Pursuant to the provisions of Article 75, paragraph 23 of our Constitution, the National State assumes the role of "guarantor" of the rights recognized in the International Treaties.

That it is precisely the National State, through this Ministry, the ultimate guarantor of the obligations assumed internationally by the Argentine Republic.

That, from the aforementioned considerations, it is possible to affirm that by means of the regulation in question, the National State, through this Health Portfolio, has fully complied with the provisions of our Magna Carta, inasmuch as it assumes the quality of "guarantor" of the rights recognized in the International Treaties, among them the right to health.

In view of the foregoing, no grievance has been identified that could support the claimant's assertions, for which reason the administrative claim filed against RESOL-2023-565-APN-MS, under the terms of Section 24, subsection a) of the National Law on Administrative Procedures No. 19,549, as amended, should be rejected, since the measure in question does not contravene the provisions of Law No. 26,687 and its Regulatory Decree No. 602/2013, under any circumstance.

That the GENERAL DIRECTION OF LEGAL AFFAIRS has taken the intervention within its competence.

That this measure is issued pursuant to the powers arising from Section 23 of Law No. 22,520, subsections 2, 31 and 34 and, Law No. 26,687 and its Regulatory Decree No. 602/2013.

Therefore,

THE MINISTER OF HEALTH

RESOLVED:

ARTICLE 1.- The improper claim filed by MASSALIN PARTICULARES S.R.L. against Resolution No. RESOL-2023-565-APN-MS dated March 23, 2023 is hereby rejected.

SECTION 2 - Let the claimant know that with the issuance of this act, administrative proceedings are exhausted, pursuant to the terms of Section 24, subsection a) of the Administrative Procedures Law No. 19,549 and Section 73 of the Administrative Procedures Regulations approved by Decree No. 1759/72 (T.O. 2017).

ARTICLE 3. Communicate, publish, send to the NATIONAL OFFICIAL REGISTRY and file.

Carla Vizzotti

e. 07/12/2023 No. 100091/23 v. 07/12/2023