

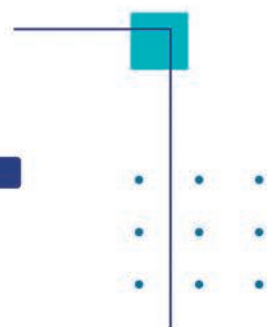
RIGHTS WITHOUT NOISE

Volume 3

How two high-ranking magistrates led historic court decisions to validate the Brazilian National Health Surveillance Agency (ANVISA) jurisdiction and regulation of the use of additives in tobacco products to protect and promote health, especially for children and adolescents

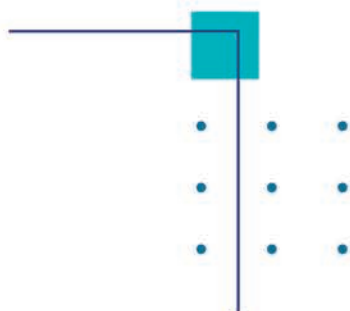
Justice Rosa Weber - Brazilian Federal Supreme Court - ADI 4874
Appeals Court Judge Daniele Maranhão - Regional Federal Court of the 1st Region - Case No. 0046408-58.2012.4.01.3300

RIGHTS WITHOUT NOISE



— Volume 3

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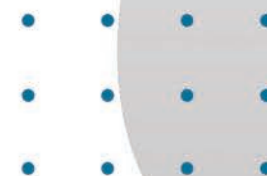
Executive direction:
Carlota Aquino Costa

Organization and proofreading:
Igor Brito

General supervision:
Carlota Aquino Costa

Layout:
Paulo Roberto Rodrigues

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Realization:

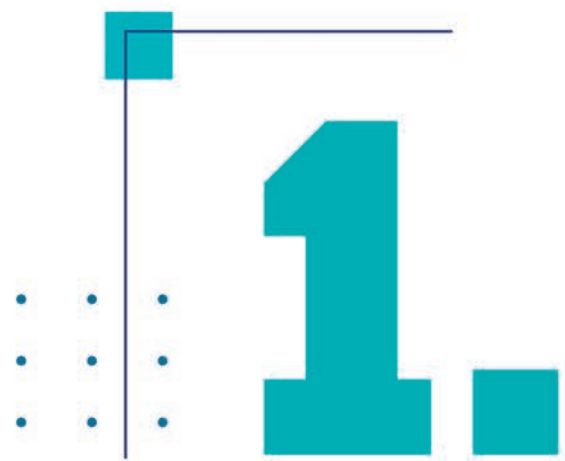


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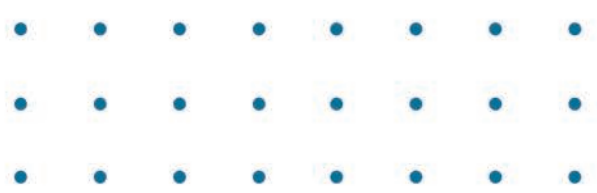
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Presentation



[PRESENTATION

Evidence shows that the tobacco industry uses additives in cigarettes and other tobacco products aiming at improving the taste and sensation of irritation caused by the product's smoke, as well as enhancing its ability to cause addiction. Some of these additives, after combustion, transform into toxic and carcinogenic substances¹. Tobacco smoke contains more than 7,000 compounds and chemical substances, and at least 69 of these compounds and substances cause cancer².

Additives such as sugar contribute as a “smoothing” agent to the smoke and can be used to mask or reduce the irritation of smoke, removing natural physiological barriers (coughing, feeling irritated, etc.). Menthol reduces irritation and works as an anesthetic component, allowing for deeper inhalations³.

“Manufacturers are clearly aware that teenagers’ first contact with cigarettes is always bad, due to the aversive effect of nicotine and the unpleasant taste of tobacco. Therefore, in recent years, the tobacco industry has introduced a wide range of aromas and flavors in specific brands and products, including cigarettes, cigars, smokeless tobacco, kreteks, bidis and hookahs. The development of products with additives to give cigarettes sweet flavors, such as sugar, honey, cherry, tutti-frutti, chocolate, among others, especially attractive to children and adolescents, seeks to make the

¹ “Aditivos em Cigarros – Notas Técnicas para Controle do Tabagismo”. Ministério da Saúde (Brazilian Ministry of Health)/Instituto Nacional do Câncer (Brazilian National Cancer Institute). 2014. <<https://www.inca.gov.br/sites/ufu.sti.inca.local/files/media/document/aditivos-em-cigarros-notas-tecnicas-para-o-controle-do-tabagismo.pdf>>

² <<https://www.gov.br/inca/pt-br/assuntos/causas-e-prevencao-do-cancer/tabagismo/tabagismo-passivo#:~:text=A%20fuma%C3%A7a%20%C3%A9%20uma%20mistura,particulada%20cont%C3%A9m%20nicotina%20e%20alcatr%C3%A3o>>

³ “Aditivos em Cigarros – Notas Técnicas para Controle do Tabagismo”. Ministério da Saúde (Brazilian Ministry of Health)/Instituto Nacional do Câncer (Brazilian National Cancer Institute). 2014. *in op.cit.*

first contact with cigarettes less aversive for this group, masking the bad taste and making the first puff easier. In other words, it aims to facilitate experimentation, paving the way for addiction and regular consumption.”

Additives also increase the toxicity of tobacco, a product that has already been proven to be harmful to health, and causes the death of up to half of its regular consumers⁴. Smoking is a disease caused by chemical dependence on nicotine, recognized by science as a toxic drug (ICD10), which makes it difficult to give up smoking. There are more than 50 diseases related to cigarette consumption⁵.

“It is already well documented that the majority of smokers identify the risk of smoking and express a desire to stop smoking. Studies show that more than 85% of those who try to quit smoking on their own relapse within a week. This dependence leads to continued tobacco use despite the negative health outcome of smoking.”⁶

The Brazilian National Health Surveillance Agency – ANVISA was created by law 9.782/1999, and has the jurisdiction to regulate, control and supervise products and services that involve risk to public health, such as cigarettes and other tobacco products.

In March 2012, after a broad and democratic public consultation process, the Brazilian National Health Surveillance Agency published Resolution of the Collegiate Board of Directors – RDC No. 14⁷, which regulates the use of additives in tobacco products. The rule provides for an exhaustive list of additives which can and cannot be used.

Society, academia and the regulated sector itself (the tobacco industry) actively participated in the entire public consultation process, and the industry’s

⁴“Aditivos em Cigarros – Notas Técnicas para Controle do Tabagismo”. Ministério da Saúde (Brazilian Ministry of Health)/Instituto Nacional do Câncer (Brazilian National Cancer Institute). 2014. *in op.cit.*

⁵<<https://bvsmms.saude.gov.br/tabagismo-13/>>

⁶“Aditivos em Cigarros – Notas Técnicas para Controle do Tabagismo”. Ministério da Saúde (Brazilian Ministry of Health)/Instituto Nacional do Câncer (Brazilian National Cancer Institute). 2014. *in op.cit.*

⁷Available at: <https://bvsmms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0014_15_03_2012.pdf>

request for permission to use sugars was accepted by Anvisa, upon proof of need (Article 7, §1).

As soon as the rule was published by the agency, the tobacco industry filed lawsuits to question Anvisa's jurisdiction and the constitutionality of the measure.

One of these lawsuits was filed with the Brazilian Federal Supreme Court by Confederação Nacional da Indústria against Anvisa (direct action of unconstitutionality – ADI No. 4874), and rapporteur Justice Rosa Weber soon decided through an injunction to suspend the rule's validity throughout the country.

The case was at a standstill for about five years, when in February 2018, a plenary trial took place, and the action was dismissed. The injunction was repealed, and the rule came back into force in the Brazilian territory.

More than two years later, in a lawsuit filed by Sindicato da Indústria do Fumo da Bahia – Sinditabaco Bahia against Anvisa, The Regional Federal Court of the 1st Region decided that the agency had jurisdiction to publish RDC 14/2012 and that the rule was constitutional, and that this decision should serve as a precedent to be followed by other cases with the same subject matter in that Court. The rapporteur of this impeccable decision was Appeals Court Judge Daniele Maranhão.

However, injunctions obtained by the tobacco industry in lawsuits have guaranteed manufacturers and importers the right not to comply with the regulation of the use of additives in tobacco products. This situation remains until the release of this publication, for over 10 years of existence of the rule.



2.

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The case



[THE CASE

In February 2018, in a plenary session of the Brazilian Federal Supreme Court, the renowned Justice Rosa Weber makes public a historic decision for tobacco control in Brazil, health promotion and protection of childhood and adolescence when she voted as rapporteur of the direct action of unconstitutionality - ADI No. 4.874.

The vote of the renowned Justice is for the dismissal of the action filed by Confederação Nacional da Indústria - CNI against the Brazilian National Health Surveillance Agency - ANVISA, by recognizing the constitutionality of both the agency's jurisdiction to prohibit the manufacture, import, storage, distribution and sale of products and inputs, in case of violation of the relevant legislation or imminent risk to health (Article 7, Item XV, of Law 9,782/1999, which creates ANVISA), and the Resolution of the Collegiate Board of Directors of the agency - RDC 14/2012, which regulates the use of additives in tobacco products.

This measure is provided for in the Framework Convention on Tobacco Control, the first public health treaty compromised with the World Health Organization, which provides a reference for tobacco control measures to be adopted by party countries. The treaty is an international commitment made by 182 countries and the European Union, like Brazil, through Decree 5,658/2006.

The regulation of the use of additives in tobacco products is a public policy that prevents smoking, contributes to cutting down on the burden of tobacco-related diseases and premature deaths, reduces the attractiveness and palatability of these products inhibiting the initiation of consumption, especially by children and adolescents, in addition to facilitating cessation. Additives, such as flavor and aromas, make it easier to take the first puff on a product that causes strong addiction, more than 70 different diseases and risk of death. There are additives that boost the addiction caused by nicotine, which make it even more difficult to quit smoking, and increase the toxicity of tobacco products.

It was the first time that the Brazilian Federal Supreme Court (STF) judged a tobacco control measure, and, by validating it, became aligned with supreme courts in countries such as United Kingdom, France, Colombia and Australia that have judged other tobacco control measures provided for in the Framework Convention on Tobacco Control to be constitutional.

The renowned Justice's vote was impeccable, very well grounded to recognize that ANVISA'S specific jurisdiction to regulate products that involve a health risk (Article 8, § 1, X, of Law No. 9,782/1999) necessarily includes the jurisdiction to define, through technical and safety criteria, the ingredients that can and cannot be used in the manufacture of such products. Hence the legal support for RDC No. 14/2012 (...).

The vote also addresses the limits of free enterprise (Articles 1, IV, and 170, caput, of the Brazilian Federal Constitution), to conclude that free enterprise does not prevent the imposition, by the State, of conditions and limits for the exploration of private activities with a view to their compatibility with other principles, guarantees, fundamental rights and constitutional, individual or social protections, with emphasis, in the case of tobacco control, on health protection and the right to information. The risk associated with tobacco consumption justifies the subjection of its market to intense health regulation, given the public interest in protecting and promoting health.

In the trial session, the Plenary followed the rapporteur Justice by majority vote, regarding Anvisa's jurisdiction, which was the main request. There was a tie on the constitutionality of the RDC 14/2012, and the Court decided to remove the binding force from the ruling on this particular issue.

As a result, the debate on the matter was allowed to be held again in the ordinary Court, and more than 40 new legal actions with the same subject matter as ADI 4874 appeared before the Federal Court of the 1st Region.

Faced with the risk of conflicting decisions, the Brazilian Attorney General's Office, which represents Anvisa, adopted an important and courageous strategy in one of these cases: request that the decision rendered served as a precedent for other legal actions within the scope of the Federal Court of the 1st Region. Thus, the so-called Incident of Assumption of Jurisdiction - IAC was presented in the case of Sindicato da Indústria do Fumo da Bahia - Sindicato tabaco Bahia (No. 0046408-58.2012.4.01.3300).

At that time, the case was awaiting trial on Anvisa's appeal, under the report of Appeals Court Judge Daniele Maranhão, at the Regional Federal Court of the 1st Region.

In the trial session of the 3rd Section of that court, in October 2020, the vote presented by the renowned Appeals Court Judge accepted the IAC, provided binding force to the precedent in relation to the fractional bodies of this Court and the first-degree magistrates.

The precedent was the Court's decision on Anvisa's appeal. Following up on the vote of the renowned Appeals Court Judge, on the merits, it was fully aligned with the vote of Justice Rosa Weber, in recognizing Anvisa's jurisdiction to regulate the use of additives in tobacco products, and to recognize the constitutionality of this measure. The plenary session unanimously followed the Appeals Court Judge's vote.

So, the Appeals Court Judge, in an impeccable and very well-founded decision, pacified the issue, the subject matter of more than 40 legal actions being processed by the TRF1, by establishing the precedent that must be followed in legal actions with the same subject matter in all instances of that court.

The decision recognizes the legality and constitutionality of RDC No. 14/2012, in alignment with the decision rendered by the STF in ADI 4874, based on the Framework Convention on Tobacco Control, which is part of Brazilian positive law; and because the act was carried out within the limits of the agency's technical jurisdiction, and in accordance with its institutional attributions.

Regarding the tie on the constitutionality of RDC 14/2012 in ADI 4874, the Appeals Court Judge concluded that the aforementioned legal action, directed at the declaration of unconstitutionality of RDC No. 14/2012, by ANVISA, was dismissed, and the injunction granted at the beginning of that action, which suspended the contested normative act, was revoked. The validity of the rule published by ANVISA results from the dismissal of the action, as the necessary quorum to withdraw its validity has not been reached, in a combined interpretation of Article 97 of the Brazilian Federal Constitution with Article 24 of Law No. 9,868/99, which regulates the direct action of unconstitutionality.

The Appeals Court Judge went on with the vote to conclude that the presumption of legality/constitutionality of the rules published by the public

authorities reinforces the conviction regarding the indication of compliance with the STF precedent.

Ten years ago, ANVISA carried out a democratic public consultation process on the regulation of the use of additives in tobacco products, which included broad participation from civil society and the regulated sector, and published RDC 14/2012. However, due to lawsuits filed by the tobacco industry and its professional associations, the rule never came into force for the largest cigarette manufacturers in the country.

The two court decisions aforementioned were historic, paradigmatic and important to strengthen Anvisa's actions and validated an important public policy for the prevention of smoking, which, at some point, will be finally implemented.

2.1 Participation of organized civil society in these cases

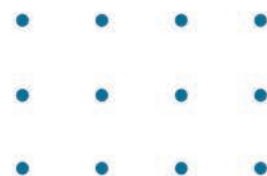

The contributions of Associação de Controle do Tabagismo, Promoção da Saúde e dos Direitos Humanos - ACT Promoção da Saúde and of Associação Mundial Antitabagismo e Antialcolismo - Amata, which acted as *amicus curiae* in ADI 4,874, contributing to the decision-making process in favor of public health, deserve to be highlighted.

In the case of TRF1, ACT Promoção da Saúde and the Brazilian Center for Health Studies - CEBES/Fiocruz have acted as collaborators in case No. 0046408-58.2012.4.01.3300, contributing to the decision-making process in favor of public health.



3.

Decision of the Plenary Session of the Brazilian Federal Supreme Court



DECISION OF THE [PLENARY SESSION OF THE BRAZILIAN FEDERAL SUPREME COURT

On the day of the trial of ADI 4,874, February 2nd, 2018, in addition to Justice Rosa Weber, Justice Cármen Lúcia, as president of the court, Justice Edson Fachin, Justice Dias Toffoli, Justice Celso de Mello, Justice Marco Aurélio, Justice Alexandre de Moraes, Justice Ricardo Lewandowski, Justice Luiz Fux and Justice Gilmar Mendes were present. Justice Roberto Barroso declared himself biased.

Justices Alexandre de Moraes, Dias Toffoli, Marco Aurélio, Gilmar Mendes, Luiz Fux voted against Justice Rosa Weber's vote regarding the constitutionality of RDC 24/2012, which led to a tie and the decision being deprived of binding effect on this point.



Justice Rosa Weber
Rapporteur of ADI 4874



Justice Celso de Mello



Justice Ricardo Lewandowski



Justice Cármen Lúcia



Justice Edson Fachin



Justice Alexandre de Moraes



Justice Dias Toffoli



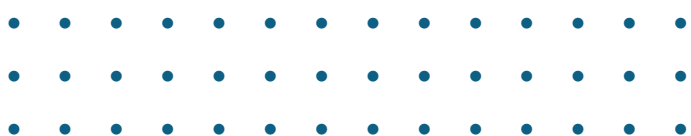
Justice Luiz Fux



Justice Marco Aurélio



Justice Gilmar Mendes



3.1 Summary

“SUMMARY: DIRECT ACTION OF UNCONSTITUTIONALITY. REQUEST FOR INTERPRETATION ACCORDING TO THE BRAZILIAN CONSTITUTION. ARTICLE 7, III AND XV, IN FINE, OF LAW NO. 9,782/1999. RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS (RDC) OF ANVISA NO. 14/2002. PROHIBITION ON THE IMPORT AND SALE OF SMOKING PRODUCTS DERIVED FROM TOBACCO CONTAINING ADDITIVES. BRAZILIAN NATIONAL HEALTH SURVEILLANCE AGENCY. SECTORAL REGULATION. NORMATIVE FUNCTION OF REGULATORY AGENCIES. PRINCIPLE OF LEGALITY. CONSTITUTIONAL ARTICLES ON FREE ENTERPRISE AND THE RIGHT TO HEALTH.

PRODUCTS THAT INVOLVE HEALTH RISK. SPECIFIC AND QUALIFIED JURISDICTION OF ANVISA. ARTICLE 8, § 1, X, OF Law No. 9,782/1999. CONSTITUTIONAL JURISDICTION. ADMINISTRATIVE DEFERENCE. REASONABILITY. FRAMEWORK CONVENTION ON TOBACCO CONTROL FCTC. DISMISSAL.

1. When establishing the Brazilian National Health Surveillance System, Law No. 9,782/1999 outlines the legal regime and defines the jurisdiction of the Brazilian National Health Surveillance Agency ANVISA, a special independent agency.
2. The normative function of regulatory agencies is not to be confused with the regulatory function of the Administration (Article 84, IV, of the Brazilian Federal Constitution), nor with the figure of autonomous regulation (Articles 84, VI, 103-B, § 4, I, and 237 of the Brazilian Federal Constitution).
3. The jurisdiction to publish normative acts aiming at the organization and supervision of regulated activities falls within the general police power of the Health Administration. ANVISA’S normative jurisdiction is qualified by publishing, in the exercise of health sector regulation, acts: (i) general and abstract, (ii) of a technical nature, (iii) necessary for the implementation of the national health surveillance policy and (iv) subject to compliance with the parameters established in the constitutional order and sectoral legislation. Precedents(...)
4. Dismissal of the request for interpretation in accordance with the Brazilian Constitution, Article 7, XV, final part, of Law No. 9,782/1999, whose univocal text absolutely attributes normative jurisdiction to prohibit products or inputs on a general and primary basis. Also dismissed is the alternative request for interpretation in accordance with the Brazilian Constitution,

Article 7, III, of Law No. 9,782/1999, which grants ANVISA normative jurisdiction conditioned on compliance with current legislation.

5. A normative act qualified by abstraction, generality, autonomy and imperativeness is entitled to the protection of constitutionality in abstracto. Cognizability of the successive request for declaration of unconstitutionality of the Resolution of the Collegiate Board of Directors (RDC) No. 14/2012 of the Brazilian National Health Surveillance Agency ANVISA.

6. Prohibition of the manufacture, import and sale, in the country, of smoking products derived from tobacco that contain substances or compounds defined as additives: compounds and substances that increase their attractiveness and the ability to cause chemical dependence. Compliance with the limits established by law and the Brazilian Constitution for the legitimate exercise by ANVISA of its normative jurisdiction.

7. Free enterprise (Articles 1, IV, and 170, caput, of the Brazilian Constitution) does not prevent the imposition, by the State, of conditions and limits for the exploration of private activities with a view to their compatibility with other principles, guarantees, fundamental rights and constitutional, individual or social protections, with emphasis, in the case of tobacco control, on health protection and the right to information. The risk associated with tobacco consumption justifies the subjection of its market to intense health regulation, given the public interest in protecting and promoting health.

8. Article 8, caput and § 1, X, of Law No. 9,782/1999 subjects smoking products, whether or not derived from tobacco, to a specific differentiated regime of regulation, control and inspection by ANVISA, as they are products that involve a risk to public health. ANVISA'S specific jurisdiction to regulate products that involve a health risk (Article 8, § 1, X, of Law No. 9,782/1999) necessarily includes the jurisdiction to define, through technical and safety criteria, the ingredients that can and cannot be used in the manufacture of such products. Hence the legal support for RDC No. 14/2012, which prohibits the addition, to smoking products derived from tobacco, of compounds or substances intended to increase their attractiveness. Of an eminently technical nature, the discipline of the form of presentation (composition, characteristics, etc.) of a product intended for consumption, does not reflect restrictions on its nature.

9. After defining the policies to be pursued, the objectives to be implemented and the objects of protection in the governing legislation, even if

a direct, precise and unambiguous statement by the legislator on the specific measures to be adopted is absent, the Judicial Branch, in exercising jurisdictional control over the exegesis conferred by an Agency on its own legal status, does not have the authority to simply replace it with its own interpretation of the law. Deference of constitutional jurisdiction to the interpretation undertaken by the administrative entity regarding the law defining its own jurisdictions and attributions, provided that the solution reached by the agency is duly substantiated and is based on an interpretation of the law that is reasonable and compatible with the Brazilian Constitution. Application of the doctrine of administrative deference (Chevron U.S.A. v. Natural Res. Def. Council).

10. The incorporation of the FCTC into domestic law, although not binding, provides a standard of reasonability for measuring the parameters adopted in RDC No. 14/2012 by ANVISA, based on the jurisdiction granted by Articles 7, III, and 8, § 1, X, of Law No. 9,782/1999.

11. By publishing the Resolution of the Collegiate Board of Directors RDC No. 14/2012, defining rules and technical standards on maximum limits of tar, nicotine and carbon monoxide in cigarettes and restricting the use of the so-called additives in smoking products derived from tobacco, without changing their nature or redefining elementary characteristics of their identity, ANVISA acted in accordance with the constitutional and legal limits of its prerogatives, subject to the constitutional article on the right to health, the current legal framework and the strict normative jurisdiction granted to it by Articles 7, III, and 8, § 1, X, of Law No. 9,782/1999. Successive request dismissed.

12. Trial quorum consisting of ten Justices, considering one prohibition to act. Nine votes for dismissing the main request for interpretation in accordance with the Brazilian Constitution, without reducing the text, Article 7, III and XV, *in fine*, of Law No. 9,782/1999. Five votes for dismissal and five for granting the successive request, without reaching a quorum of six votes (Article 23 of Law No. 9,868/1999) absolute majority (Article 97 of the Brazilian Constitution) to declare the unconstitutionality of RDC No. 14/2012 of ANVISA, to deprive the decision on trial of its binding effect, in the matter.

13. Direct action of unconstitutionality heard, and, on the merits, the main requests and the successive request were dismissed. Judgment devoid of binding effect only regarding the successive request, as the quorum for the declaration of the constitutionality of the Resolution of the Collegiate Board of Directors No. 14/2012 of ANVISA has not been reached”.

PLENARY SESSION

CERTIFICATE OF JUDGMENT

DIRECT ACTION OF UNCONSTITUTIONALITY 4,874

PROCEEDING: FEDERAL DISTRICT

RAPPORTEUR: JUSTICE ROSA WEBER

PLAINTIFF(S): CONFEDERACAO NACIONAL DA INDUSTRIA

ATTORNEY(S): ALEXANDRE VITORINO SILVA (15774/DF)

INTERESTED PARTY (IES): BRAZILIAN PRESIDENT

INTERESTED PARTY (IES): BRAZILIAN NATIONAL CONGRESS

ATTORNEY(S): BRAZILIAN ATTORNEY GENERAL

AM. CURIAE: SINDICATO DA INDÚSTRIA DO TABACO NO ESTADO DA BAHIA - SINDITABACO/BA

ATTORNEY(S): JULIANO REBELO MARQUES (159502/SP) AND OTHERS

AM. CURIAE: SINDICATO INTERESTADUAL DA INDÚSTRIA DO TABACO - SINDITABACO

ATTORNEY(S): BRUNO BESERRA MOTA (24132/DF) AND OTHERS

AM. CURIAE: ASSOCIAÇÃO MUNDIAL ANTITABAGISMO E ANTIALCOOLISMO - AMATA

ATTORNEY(S): SERGIO TADEU DINIZ (098634/SP)

ATTORNEY(S): LUÍS RENATO VEDOVATO (142128/SP)

ATTORNEY(S): AMANDA FLÁVIO DE OLIVEIRA (72110/MG)

AM. CURIAE: ASSOCIAÇÃO DE CONTROLE DO TABAGISMO, PROMOÇÃO DA SAÚDE E DOS DIREITOS HUMANOS - ACT

ATTORNEY(S): CLARISSA MENEZES HOMSI (131179/SP) AND OTHERS

AM. CURIAE: FEDERAÇÃO NACIONAL DOS TRABALHADORES DA INDÚSTRIA DO FUMO E AFINS - FENTIFUMO

ATTORNEY(S): JOÃO PEDRO FERRAZ DOS PASSOS (1663A/DF) AND OTHERS

AM. CURIAE: ABIFUMO - ASSOCIAÇÃO BRASILEIRA DA INDÚSTRIA DO FUMO

ATTORNEY(S): ANDRÉ CYRINO (123111/RJ) AND OTHERS

I **HEREBY CERTIFY** that the **PLENARY SESSION**, when considering the case referred to above, in a session held on this date, rendered the following decision:

Decision: After the report and oral arguments, the trial was suspended. Justice Ricardo Lewandowski was absent, with justification. The following had the floor: for plaintiff, Confederação Nacional da Indústria – CNI, Dr. Alexandre Vitorino Silva; for the Brazilian President and the Brazilian National Congress, Justice Grace Maria Fernandes Mendonça, Brazilian Attorney General; for the *amicus curiae* Sindicato Interestadual da Indústria do Tabaco – SINDITABACO, Dr. Carlos Eduardo Caputo Bastos; for the *amicus curiae* Associação Brasileira da Indústria do Fumo – ABIFUMO, Dr. Gustavo Binenbojm; for the *amicus curiae* Associação Mundial Antitabagismo e Antialcoolismo – AMATA, Dr. Luis Renato Vedovato and Dr. Amanda Flávio de Oliveira; and, for the *amicus curiae* Associação de Controle do Tabagismo Promoção da Saúde e dos Direitos Humanos – ACT, Dr. Walter José Faiad de Moura. Presided over by Justice Cármen Lúcia. Plenary Session, November 9th, 2017.

Decision: The Court unanimously heard the direct action, in accordance with the Rapporteur’s vote. On the merits, regarding the main request, for declaring the unconstitutionality of Article 7, III, and XV, *in fine*, of Law 9,782/1999, by majority and in accordance with the Rapporteur’s vote, the Court dismissed the request, and Justice Marco Aurélio was partially defeated. Regarding the successive requests, relating to the rules of the Resolution of the Collegiate Board of Directors of ANVISA 14/2012, the Court dismissed the action, in a trial devoid of binding effect and *erga omnes* effects, as the *quorum* required by Article 97 of the Brazilian Constitution had not been reached, with the injunction granted being revoked, in accordance with the Rapporteur’s vote. Minister Roberto Barroso declared himself biased. The trial was presided over by Justice Cármen Lúcia. Plenary Session, February 1st, 2018.

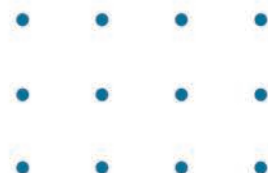
Presided over by Justice Cármen Lúcia. The following Justices attended the session: Celso de Mello, Marco Aurélio, Gilmar Mendes, Ricardo Lewandowski, Dias Toffoli, Luiz Fux, Rosa Weber, Roberto Barroso, Edson Fachin and Alexandre de Moraes.

Brazilian Prosecutor General, Dr. Raquel Elias Ferreira Dodge.

for Doralúcia das Neves Santos
Chief Assistant of the Plenary Session



**Decision 3rd
Section of
the Regional
Federal Court
of the
1st Region**



DECISION 3rd SECTION OF THE REGIONAL FEDERAL COURT OF THE 1st REGION

On the day of the trial of the appeal and the IAC, in case No. 0046408-58.2012.4.01.3300, in addition to the rapporteur Appeals Court Judge Daniele Maranhão, the Federal Appeals Court Judges Jirair Aram Meguerian, Daniel Paes Ribeiro, João Batista Moreira, Souza Prudente and Carlos Augusto Pires Brandão were present.



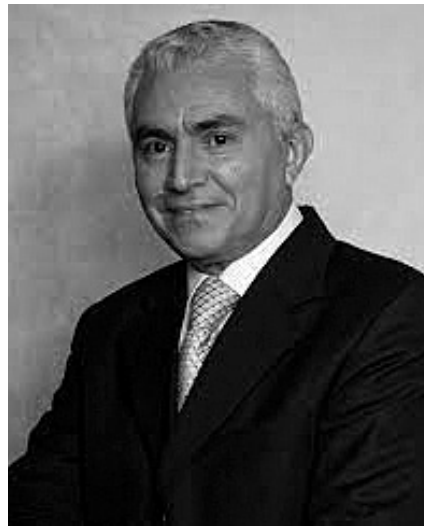
Appeals Court Judge Daniele Maranhão
The appeal and IAC rapporteur



Appeals Court Judge Jirair Aram Meguerian



Appeals Court Judge Souza Prudente



Appeals Court Judge Daniel Paes Ribeiro



Appeals Court Judge Carlos Pires Brandão



Appeals Court Judge João Batista Moreira



4.1 Summary

“CONSTITUTIONAL AND CIVIL PROCEDURAL LAW. RDC No. 14/2012-ANVISA. ARTICLES 6 AND 7. PROHIBITION OF ADDITIVES IN TOBACCO PRODUCTS. PROPOSAL FOR ASSUMPTION OF JURISDICTION. ADMISSIBILITY. ARTICLE 947 OF THE BRAZILIAN CODE OF CIVIL PROCEDURE (CPC) AND ARTICLE 363 OF REGIONAL FEDERAL COURT INTERNAL REGULATIONS (RITRF) - 1st REGION. ADI No. 4874. DISMISSED BY THE STF. PRESUMPTION OF CONSTITUTIONALITY OF NORMATIVE ACTS OF THE PUBLIC AUTHORITIES. FRAMEWORK CONVENTION ON TOBACCO CONTROL. RULE INTEGRATED INTO BRAZILIAN POSITIVE LAW. LEGISLATIVE DECREE No. 1,012/2005 AND DECREE No. 5,658/2006. FORCE OF LAW. NO OFFENSE TO THE PRINCIPLE OF LEGAL RESERVE. REVERSED JUDGMENT.

1. The controversy over the validity or otherwise of the Resolution of the Collegiate Board of Directors – RDC No. 14/2012, of ANVISA, an issue discussed in the case, ends discussion on an important question of law, with great social repercussion, and there is no repetition in multiple cases, in addition to the constitution of the possibility of divergent decisions, given the result of the trial of ADI No. 4874, which does not have an *erga omnes* binding effect.

2. Admissibility of the Incident of Assumption of Jurisdiction – IAC, in order to give binding force to this precedent in relation to the fractional bodies of this Court and the first-degree magistrates, in accordance with the provisions of Article 947 of the Brazilian Code of Civil Procedure (CPC) and Article 363 of the Internal Regulations of this Court.

3. Not hearing of the Internal Appeals filed against the decision that did not admit the entry of an *amicus curiae* to the dispute, raised to the Collegiate Board as a point of order, given the literalness of Article 138 of the Brazilian Civil Procedure Code regarding the unappealable nature of the judicial pronouncement that admits or not the procedural figure, following the interpretation given to the debate by the Brazilian Superior Court of Justice and the Brazilian Federal Supreme Court. (STJ, Question of Order in Special Appeal (REsp) 1.696.396/MT, Rapporteur Justice Nancy Andrighi, Special Court, Electronic Justice Gazette (DJe) dated December 19th, 2018 and STF, in plena-

ry session, in the trial of Extraordinary Appeal (RE) 602.584/DF, on October 17th, 2018).

4. Although the result of the trial of ADI No. 4874 by the Brazilian Federal Supreme Court does not confer binding effect and *erga omnes* effects to the precedent, given the tie in the trial, 5 X 5, the aforementioned action, directed at the declaration of unconstitutionality of RDC No. 14/2012, by ANVISA, was dismissed, and the injunction granted at the beginning of that action, which suspended the contested normative act, was revoked. The validity of the rule published by ANVISA results from the dismissal of the action, as the necessary quorum to withdraw its validity has not been reached, in a combined interpretation of Article 97 of the Brazilian Federal Constitution with Article 24 of Law No. 9,868/99, which regulates the direct action of unconstitutionality.

5. The application of the Sole Paragraph of Article 23 of Law No. 9,868/99 is rejected, considering that the tie originated from the biased position declared by Justice Roberto Barroso, with the STF, on the date of the trial, having its full composition.

6. The presumption of legality/constitutionality of the rules issued by the Public Authorities reinforces the conviction regarding the indication of compliance with the STF precedent.

7. It should be added that, on the issue discussed, prohibition of additives with flavoring or aromatizing properties in tobacco products, the Framework Convention on Tobacco Control is included, as ratified by the Brazilian State, approved by the Brazilian National Congress by Legislative Decree No. 1,012/2005 and promulgated by the Brazilian President pursuant to Decree No. 5,658/2006, in which the signatory countries committed to adopting measures aimed at banning substances that aim to give the product greater palatability, among other restrictions, which expressly addresses the topic: *“Parties must regulate, prohibiting or restricting, ingredients that can be used to increase the palatability of tobacco products. (...)”*

8. The international treaty, regularly incorporated into Brazilian positive law, has the force of law (ADI 480-3/DF), so that any understanding of the need for law to authorize ANVISA to publish the normative act in question would be met by the international standard

introduced into the Brazilian legal system. Therefore, the allegation of infringement of the principle of legal reserve is ruled out.

9. Taking care of the blank standard, it is up to each signatory country to adopt the necessary measures in order to comply with the agreed terms, regulating prohibitions and restrictions.

10. In the case of Brazil, this responsibility is constitutionally and legally conferred on ANVISA, the technical body responsible for regulating issues involving health risks, in accordance with the provisions of Articles 7 and 8 of Law No. 9,782/99, which established the regulatory agency and gave it jurisdiction for said purpose.

11. The existence of the international treaty to which Brazil is a signatory eliminates the need to prove the imminent risk to health referred to in Article 7, XV, of Law No. 9,782/2009, to the extent that the agency's intervention would have taken place within the activities authorized and agreed upon in the treaty.

12. Recognition of the legality/constitutionality of RDC No. 14/2012, by ANVISA, in line with the understanding proposed by the STF in ADI No. 4874; due to the enforceability of the Framework Convention on Tobacco Control, which is part of Brazilian positive law; and because the act was carried out within the limits of the agency's technical jurisdiction, and in accordance with its institutional functions.

13. Internal Appeals not heard, given the unappealable nature of the decision that does not allow the entry of an *amicus curiae*.

14. ANVISA appeal and necessary transfer that is granted to dismiss the action. ANVISA appeal and necessary transfer that is granted to dismiss the action. Reversed judgment. judgment.

CERTIFICATE OF JUDGMENT

8th ORDINARY SESSION OF THE THIRD SECTION HELD
ON OCTOBER 20th, 2020

President of the Session: Hon. Federal Appeals Court Judge DANIELE MARANHÃO

Brazilian Regional Federal Prosecutor: Hon. Dr. GUSTAVO PESSANHA VELLOSO

Secretary: AUGUSTO CÉSAR DA SILVA RAMOS

Rapporteur: FEDERAL APPEALS COURT JUDGE DANIELE MARANHÃO

Case No. 0046408-58.2012.4.01.3300

INCIDENT OF ASSUMPTION OF JURISDICTION (12087)

CLAIMANT: BRAZILIAN NATIONAL HEALTH SURVEILLANCE AGENCY and others (2)

RESPONDENT: SINDICATO DA INDUSTRIA DO TABACO NO ESTADO DA BAHIA

CERTIFICATE

I hereby certify that the distinguished 3rd Section, when considering the case referred to above, in a session held on October 20th, 2020, rendered the following decision:

Unanimously, the Section did not hear the internal appeals filed against the decision that did not admit the entry of an *amicus curiae*; unanimously accepted the incident of Assumption of jurisdiction and, on the merits, also unanimously, granted ANVISA'S appeal and the necessary transfer, in accordance with the Rapporteur's vote.

Oral argument:

Dr. Thiago Cássio D'Ávila Araújo, OAB/DF 25028, for ANVISA;

Dr. Walter José Faiad de Moura, OAB/DF 17.390, assistant

Dr. Adriana Carvalho OAB/SP 148.379, assistant, both for Associação de Controle do Tabagismo, Promoção da Saúde e dos Direitos Humanos - ACT and CEBES;

Dr. Carlos Eduardo Caputo Bastos, OAB/DF 2.462, for Sindicato da Indústria do Tabaco no Estado da Bahia - SINDITABACO/BA and

Dr. Gustavo Pessanha Velloso, for the Brazilian Federal Public Prosecutor's Office.

The following Hon. Federal Appeals Court Judges attended the Trial Session:

The Hon. Federal Appeals Court Judges Jirair Aram Meguerian, Daniel Paes Ribeiro, João Batista Moreira, Souza Prudente, Carlos Augusto Pires Brandão and Daniele Maranhão attended the trial, held in a face-to-face session with video support.

Note: this certificate of judgment replaces the previous certificate, in view of the oral arguments.

AUGUSTO CESAR DA SILVA RAMOS
Secretary of the Session



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Defesa do Consumidor

