

# BUSINESS REVIEW

### CIVIL AND CRIMINAL LIABILITY FOR QUALITY AND SAFETY VIOLATIONS IN THE TOBACCO INDUSTRY

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#### **ABSTRACT**

**Purpose:** This study aims to examine the legal liability of tobacco companies regarding violations of quality and safety laws, with a focus on how these violations impact public health and community safety. The research seeks to provide a comprehensive analysis of the legal mechanisms available to hold these companies accountable and impose appropriate penalties.

**Theoretical Framework:** The study is based on a review of legal and health literature addressing the impact of tobacco products on public health, along with an analysis of the policies and regulations governing the tobacco industry. The research highlights the challenges in enforcing quality and safety laws and suggests ways to overcome them to enhance consumer protection.

**Design/Methodology/Approach:** An analytical methodology was employed, focusing on the study of judicial cases related to tobacco company violations. Data was collected from reliable legal sources and international health reports, and the legal experiences of various countries were reviewed to understand how they have dealt with tobacco company violations.

**Findings:** The findings revealed significant disparities in the enforcement of quality and safety laws on tobacco companies across different countries. It was found that companies often exploit legal loopholes to avoid stringent penalties. However, some countries have successfully reduced health damages by imposing strict penalties and raising public awareness about the risks of tobacco.

**Research, Practical & Social Implications:** The study demonstrates that strengthening the enforcement of laws related to the quality and safety of tobacco products can significantly reduce the severe health impacts caused by smoking. The research provides recommendations for improving public policies and encouraging collaboration between legal and health authorities to achieve better consumer protection.

**Originality/Value:** The value of this study lies in presenting a comprehensive perspective on the necessity of enhancing the legal accountability of tobacco companies. It highlights the importance of developing stringent and integrated laws that address the current challenges in the tobacco industry, contributing significantly to improving public health and community safety.

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### RESPONSABILIDADE CIVIL E CRIMINAL POR VIOLAÇÕES DE QUALIDADE E SEGURANÇA NA INDÚSTRIA DO TABACO

#### **RESUMO**

**Objetivo:** este estudo tem como objetivo examinar a responsabilidade legal das empresas de tabaco em relação às violações das leis de qualidade e segurança, com foco em como essas violações afetam a saúde pública e a segurança da comunidade. A pesquisa busca fornecer uma análise abrangente dos mecanismos legais disponíveis para responsabilizar essas empresas e impor penalidades adequadas.

Estrutura Teórica: O estudo baseia-se em uma revisão da literatura jurídica e de saúde que aborda o impacto dos produtos de tabaco na saúde pública, juntamente com uma análise das políticas e regulamentações que regem a indústria do tabaco. A pesquisa destaca os desafios na aplicação das leis de qualidade e segurança e sugere maneiras de superá-los para aumentar a proteção do consumidor.

**Projeto/Metodologia/Abordagem:** Foi empregada uma metodologia analítica, com foco no estudo de casos judiciais relacionados a violações de empresas de tabaco. Os dados foram coletados de fontes jurídicas confiáveis e relatórios internacionais de saúde, e as experiências jurídicas de vários países foram analisadas para entender como eles lidaram com as violações das empresas de tabaco.

**Conclusões:** Os resultados revelaram disparidades significativas na aplicação das leis de qualidade e segurança das empresas de tabaco em diferentes países. Descobriu-se que as empresas frequentemente exploram brechas legais para evitar penalidades rigorosas. No entanto, alguns países conseguiram reduzir os danos à saúde impondo penalidades rigorosas e aumentando a conscientização pública sobre os riscos do tabaco.

Implicações Sociais, Práticas e de Pesquisa: O estudo demonstra que o fortalecimento da aplicação de leis relacionadas à qualidade e à segurança dos produtos de tabaco pode reduzir significativamente os graves impactos à saúde causados pelo tabagismo. A pesquisa fornece recomendações para aprimorar as políticas públicas e incentivar a colaboração entre as autoridades legais e de saúde para obter melhor proteção ao consumidor.

**Originalidade/valor:** O valor deste estudo está no fato de apresentar uma perspectiva abrangente sobre a necessidade de aumentar a responsabilidade legal das empresas de tabaco. Ele destaca a importância de desenvolver leis rigorosas e integradas que abordem os desafios atuais do setor de tabaco, contribuindo significativamente para melhorar a saúde pública e a segurança da comunidade.

**Palavras-chave:** Tabaco, Responsabilidade Legal, Qualidade e Segurança do Produto, Saúde Pública, Políticas Legais, Violações Corporativas, Penalidades Legais.

### RESPONSABILIDAD CIVIL Y PENAL POR INFRACCIONES EN MATERIA DE CALIDAD Y SEGURIDAD EN LA INDUSTRIA DEL TABACO

#### **RESUMEN**

**Propósito:** Este estudio pretende examinar la responsabilidad legal de las empresas tabaqueras en relación con las infracciones de las leyes de calidad y seguridad, centrándose en cómo afectan estas infracciones a la salud pública y a la seguridad de la comunidad. La investigación pretende ofrecer un análisis exhaustivo de los mecanismos legales disponibles para responsabilizar a estas empresas e imponerles las sanciones adecuadas.

**Marco Teórico:** El estudio se basa en una revisión de la literatura jurídica y sanitaria que aborda el impacto de los productos del tabaco en la salud pública, junto con un análisis de las políticas y normativas que rigen la industria tabacalera. La investigación pone de relieve los retos que plantea la aplicación de las leyes sobre calidad y seguridad y sugiere formas de superarlos para mejorar la protección de los consumidores.

**Diseño/Metodología/Enfoque:** Se empleó una metodología analítica, centrada en el estudio de casos judiciales relacionados con infracciones de las empresas tabaqueras. Se recopilaron datos de fuentes jurídicas fiables e informes sanitarios internacionales, y se revisaron las experiencias jurídicas de varios países para comprender cómo han abordado las infracciones de las empresas tabaqueras.

**Resultados:** Los resultados revelaron disparidades significativas en la aplicación de las leyes de calidad y seguridad a las empresas tabacaleras en los distintos países. Se constató que las empresas suelen aprovecharse de las lagunas legales para evitar sanciones estrictas. Sin embargo, algunos países han conseguido reducir los daños a la salud imponiendo sanciones estrictas y concienciando a la población sobre los riesgos del tabaco.

**Investigación e Implicaciones Prácticas y Sociales:** El estudio demuestra que el refuerzo de la aplicación de las leyes relacionadas con la calidad y la seguridad de los productos del tabaco puede reducir significativamente los graves efectos sobre la salud causados por el tabaquismo. La investigación ofrece recomendaciones para mejorar las políticas públicas y fomentar la colaboración entre las autoridades jurídicas y sanitarias para lograr una mejor protección de los consumidores.

**Originalidad/Valor:** El valor de este estudio radica en la presentación de una perspectiva global sobre la necesidad de mejorar la responsabilidad legal de las empresas tabaqueras. Destaca la importancia de elaborar leyes rigurosas

e integradas que aborden los retos actuales de la industria tabacalera, contribuyendo significativamente a mejorar la salud pública y la seguridad de la comunidad.

**Palabras clave:** Tabaco, Responsabilidad Jurídica, Calidad y Seguridad de los Productos, Salud Pública, Políticas Jurídicas, Infracciones Empresariales, Sanciones Legales.

### 1 INTRODUCTION

Legal responsibility plays a vital role in guiding, controlling and encouraging the tobacco industry towards a strong commitment to quality and safety. By taking a regulatory, prescriptive and preventive approach, producers are encouraged to adopt higher standards of quality and improve the safety of their products. In the event of a violation of these standards, the producer shall bear legal, civil and criminal liability for any harm that may be caused to consumers or to society in general.

While following standards of reasonable conduct reflects compliance with the law, failure to take necessary measures to mitigate risks and ensure product safety can lead to serious legal consequences.

Throughout the world, legal liability for violations of quality and safety laws in the tobacco industry is a vital and pivotal issue. Laws and regulations vary from one country to another, and among the countries that pay great attention to this matter, Italy stands out as one of the examples. Italian law regulates a number of laws and legislation that stipulate the legal responsibility of tobacco producing companies when it comes to violating quality and safety standards. For example, Italy's public health law mandates adherence to strict standards to ensure the quality and safety of tobacco products, with legal penalties imposed on companies that violate these standards. Through this legal approach, companies are incentivized to take the necessary measures to comply with legal standards and keep consumers safe. Although legislation varies from country to country, the overall goal is to achieve higher levels of quality and safety in the tobacco industry globally.

### 2 THE CONCEPT OF QUALITY AND SAFETY IN THE TOBACCO INDUSTRY

### 2.1 THE HISTORY OF TOBACCO AND SOME OF ITS PRODUCTS

Tobacco is a plant belonging to the pea genus, which contains nicotine, which is considered an irritant to the central nervous system in humans. Tobacco is widely used in the smoking industry, either as a dried and processed plant to manufacture cigarettes, or as a plant used in pipe smoking or individual cigarettes. Its cultivation is widespread in the temperate tropical and subtropical regions, with the American continent being its original homeland. Water constitutes about 90 percent of its weight.

Nicotine is a substance in tobacco found in cigarettes, cigars, pipes, and chewing tobacco, as well as cigarettese) to which users are addicted. In addition to nicotine, cigarettes contain tar and carbon monoxide, as well as about 4,000 other ingredients, many of which are toxic. Nicotine is also the active ingredient in some drug products that are used to help people quit smoking. When a person gets nicotine from smoking cigarettes, it reaches the brain quickly (within 10 seconds) and is thus highly addictive. In contrast, delivery of nicotine via transdermal patch is slow, steady, and non-addictive. Its most important products are: shisha, pipes, and cigars.

The Algerian Health Law also stipulates in Article 54 that: "Items intended for smoking, inhaling, placing on the gums, chewing or sucking, including electronic cigarettes, are considered tobacco materials as long as they contain tobacco, even partially."

### 2.2 QUALITY IN THE CONTEXT OF THE TOBACCO INDUSTRY

International quality standards mean the quantitative and qualitative standards that a good, product, or service must have. Specifications and standardization bodies in various countries are issued by specialized experts and scientists. As for international standards, they are issued by ISO. International standards are always preceded by the International Organization for Standardization (ISO) symbol. It is known as "A set of written specifications that describe internationally recognized protocols for the operation, modeling, performance and management of production and commodity processes." (Edmond, 1993, p. 41).

Covers ISO 6488 Standardization of terminology and test methods for tobacco smoke, including unprocessed tobacco, all types of tobacco products, materials used in the manufacture of tobacco products, and environmental aspects of tobacco smoke.

The collected cigarettes are subjected to statistical checks for weight and unit (ISO 2971), shape and drag resistance (ISO 6565), and ventilation (ISO 9512). The Standardization Organization for the Arab Gulf Cooperation Council (GCC), within the work program of Technical Committee No. TC05 SC4 "Gulf Technical Subcommittee for Tobacco Products Standards," is preparing Gulf Standard Specification No. GSO for "Hand-rolling tobacco." The

Kingdom of Saudi Arabia has prepared a draft of this standard. Among the most important requirements for the product are:

The tobacco used to prepare hand-rolling tobacco must meet the following requirements:

- it must be clean and free of parasites, viral infections, germs, mold, insects and foreign materials:
- the tobacco manufacturing or processing process must be carried out in a way that does
  not cause any negative effects on the quality of smoking, and the tobacco left over from
  the smoking process must not have been subjected to any process that would change the
  basic characteristics of the final product in the manufacturing process;
- the percentage of additives to the tobacco used in manufacturing cigarettes shall not exceed 1.0% on a dry weight basis and shall not increase the harmful effects on health when burned<sup>1</sup>.

Regulation of tobacco products is still nascent in many regions of the world, but the WHO Framework Convention on Tobacco Control has paved the way and laid the foundations for future regulation of the contents, emissions, disclosure, packaging and labeling of tobacco products.

### 2.3 SAFETY STANDARDS FOR TOBACCO PRODUCTS IN ALGERIA:

Since tobacco products are considered naturally dangerous products, the legislative authorities in Algeria have imposed on their producers, importers, and even distributors, the necessity of obtaining a prior license from the authority controlling the tobacco market. This commitment comes in accordance with the provisions of Article 5 of Executive Decree No. 04\_331 relating to regulating the activities of manufacturing, importing and distributing tobacco materials, which stipulates the necessity of obtaining a prior license before starting the activity."

As stated in the Appendix to the Book of Conditions, the producer must commit to respecting the strict provisions contained in the articles of this Appendix, including those stipulated in Article 2 of this Appendix, as the latter required the tobacco manufacturer to write a statement stating: the field of activity, and the technology. Used modern items, conditions for maintaining the environment, security procedures, and other conditions.

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<sup>&</sup>lt;sup>1</sup> Standardization Organization for the Arab States of the Gulf Cooperation Council, Tobacco Standardization Project, Manual Rolling.

As stated in the Algerian health law<sup>2</sup> In Article 52: "In marketing tobacco products, it is required that a general warning be written on the visible side of the package in large letters that includes the following phrase: "Tobacco consumption is harmful to health."

For cigarette packs, the other large side of the package must include, in addition to the general warning, a special warning in the form of drawings or pictorial symbols issued by the health authority.

And in Article 53: "In addition to the health warnings stipulated in Article 52 above, all forms of packaging of tobacco materials and the labels affixed to them must include data on the basic toxic compounds and their secretions. The data stipulated in the above paragraph shall be determined by regulation.".

Article 55: "Producers and importers of tobacco materials must inform the competent authorities in this field of all information related to the composition of tobacco materials and their secretions, who must carry out the necessary investigations in accordance with the applicable standards and standards."

In these aforementioned articles, the Algerian legislator is keen on the necessity of ensuring safety in the production and manufacture of tobacco in accordance with the standards adopted in this regard.

There are several well-known occupational hazards associated with tobacco cultivation, including green tobacco sickness, pesticide poisoning, respiratory and skin disorders, and cancer in certain locations. Green tobacco disease, specifically a tobacco-related disease, is caused by the absorption of nicotine through the skin, which is exacerbated by handling wet leaves, but can be prevented by using personal protective equipment. However, lack of knowledge, limited access to resources, the quest to reduce production costs and climatic conditions restrict the use of PPE. Moreover, women and children are often the most vulnerable to health risks: this category is often used due to the labor-intensive nature of the crop, the small size of the farms, and the precise skills required for some tasks. Moreover, rolling a bidi requires sitting for long hours in a certain position, which leads to musculoskeletal problems. Article 8 of the World Health Organization Framework Convention stipulates that:

- the Parties acknowledge that scientific evidence has proven beyond doubt that exposure to tobacco smoke causes death, disability and disease;
- each Party shall adopt, implement and promote effectively, in areas under its national jurisdiction as determined by national laws and at all levels of jurisdiction, legislative,

<sup>&</sup>lt;sup>2</sup> Law No. 18-11 of July 2, 2018 relating to health.

executive, administrative or other measures that provide protection from exposure to tobacco smoke in indoor workplaces, public transportation and indoor public spaces As necessary, and other public places.

## 3 INTERNATIONAL AND NATIONAL LEGISLATION AND LAWS REGULATING THE TOBACCO INDUSTRY

The tobacco industry faces significant challenges in regulating quality standards due to several interrelated factors. First and foremost, the tobacco industry is a major economic sector, with an important influence on the economy and legislation in many countries. Therefore, it has a great ability to influence the process of formulating policies and laws. Second, tobacco companies exert strong economic and political pressure to protect their interests, and may have significant influence in directing government policies and shaping legislation related to the tobacco industry. International coordination also poses a major challenge in applying strict international standards to control the quality of tobacco products, given the differences in interests and preferences between countries. In addition, challenges related to tax evasion and illegal trade include the difficulty of enforcing laws and activating product quality control.

Regulation of tobacco products through health surveillance (HS) is an example. HS is certainly one of the oldest areas of public health, and its history is intertwined with the history of human civilization. Egyptian, Chinese, Hindu, Greek and Roman civilizations provide records of HS procedures, especially in the field of food control.

### 3.1 INTERNATIONAL AGREEMENTS RELATED TO QUALITY AND SAFETY IN THE TOBACCO INDUSTRY

Among the international agreements that have attempted to regulate quality and safety standards for tobacco production, emphasis can be placed on the World Health Organization's Tobacco Control Convention (FCTC). Adopted in 2003 and entering into force in 2005, this agreement is the first international health agreement aimed at controlling smoking and the consumption of tobacco products. The agreement aimsThe FCTC seeks to achieve several goals, including regulating the production and marketing of tobacco products in a way that achieves public health and protects society from the effects of smoking. The Convention has taken a set of measures and directives to achieve these goals, including:

- regulating the advertising and marketing of tobacco products;
- establish guidelines for health warnings on tobacco product packaging;
- regulating the use of chemicals and hazardous materials in the tobacco production process;
- strengthening oversight of the tobacco industry and implementing taxes on it;
- supporting smoking cessation programs and raising awareness of its dangers.

However, the application of the Convention FCTC entails numerous challenges, including resistance from the tobacco industry and its lobbies, as well as the difficulty of standardizing legislation and implementation across national borders. Furthermore, there is a range of regional and national agreements and legislation that aim to regulate the tobacco industry and the quality of its products, including occupational safety and health laws and legislation related to quality, manufacturing and product marketing.

Also the International Labor Organization (ILO) It is a United Nations agency working to achieve social justice and promote decent work opportunities around the world. Play ILO plays an important role in setting and implementing international standards for work and occupational safety, and this includes sectors that may be relevant to the tobacco industry. Through its conferences and agreements, ILO works to establish international standards for occupational safety and health, which also include sectors that produce tobacco. These standards encourage the provision of a safe and healthy work environment for workers in all industries, including providing preventive measures to reduce the risks of exposure to hazardous materials and passive smoking, and providing training and awareness of potential risks.

For the tobacco industry, standards set by ILO should include a range of aspects such as the safety of the production process, protecting workers from harmful chemicals used in tobacco manufacturing, and ensuring environmental safety in factories. By collaborating with governments, labor organizations and the tobacco industry itself, ILO seeks to strengthen the application of these standards and enhance awareness of their importance to ensure a healthy and safe working environment for all workers in the sector.<sup>3</sup>

The World Health Organization Conference on Expanding Knowledge on the Regulation of Tobacco Products, which was held in Oslo, urged the establishment of a unified

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<sup>&</sup>lt;sup>3</sup> Recommendation No. 151 of the International Labor Conference, 91st session in 2003, states that "Convention No. 155 applies to all branches of economic activity and all workers in these branches, and requires Member States to formulate and implement a coherent national policy on occupational safety, occupational health and the working environment and to review it periodically." Objective This policy (Article 4) is to prevent accidents and health damage resulting from, related to, or occurring during work, by reducing the causes of risks involved in the work environment to the greatest extent possible and reasonable."

regulatory framework for products containing nicotine, including tobacco products, to reduce dependence on tobacco, and to promote methods that help educate people about the best ways to treat tobacco products. Addiction to tobacco, as well as obligating tobacco product manufacturers to do what is required regarding clearly stating the content of their products and their negative effects. The participants in this conference in support of the draft Framework Convention on Tobacco Control recognized the need for countries to have general policies and strategies to combat tobacco and regulate its production within a set of foundations, including Having a standard for evaluating products on the market, and constantly reminding manufacturers to state the negative effects of tobacco on health and safety<sup>4</sup>.

It is also worth noting that with regard to electronic cigarettes, a report issued by the World Health Organization, at the Conference of the Parties to the Framework Convention on Tobacco Control, stated, "The report indicated that manufacturers claim that these products are released without tar or carbon monoxide, and concluded that "There is no evidence of the safety and range of nicotine intake or that these products are marketed as an aid to tobacco cessation and that there is no scientific evidence to substantiate these claims." 5

Some guidelines require manufacturers and importers of tobacco products, in order to apply these provisions, to:

- disclosure of information regarding componentes;
- tobacco products for government authorities, including additives;
- submit a statement to government authorities of the purpose;
- list every component of the tobacco product. And other relevant information;
- members are also urged to ban or restrict ingredients that may be used to increase palatability;
- ban or restrict coloring agents in tobacco products that increase their attractiveness;
- prohibit ingredients in tobacco products that may create the impression of a health benefit, including increased energy and vitality<sup>6</sup>.

The European Union issued several European directives to regulate the production and marketing of tobacco products, including:

<sup>&</sup>lt;sup>4</sup> World Health Organization, second meeting of the working group on the WHO Framework Convention on Tobacco Control provisional agenda and timetable, –Geneva, October 25 - 29, 1999A/FCTC/WG1/:

<sup>&</sup>lt;sup>5</sup> Conference of the Parties to the WHO Framework Convention on Tobacco Control, fourth session, September 2010

<sup>&</sup>lt;sup>6</sup> WHO Framework Convention on Tobacco Control: Guidelines for implementation Article 5.3; Article 8; Article 9 and 10; Article 11; Article 12; Article 13; Article 14. Geneva; 2013.

- European Directive No. 29 of 2005 prohibiting all acts and commercial practices that
  mislead the consumer and prohibiting advertisements and commercial advertisements
  for light and less toxic cigarettes, on the grounds that such advertisements give a false
  impression and are considered a deceptive commercial practice;
- European Directive No. 40 of 20147In its first article, it stipulated that the percentages of tar, nicotine, and carbon monoxide in cigarettes must be printed on one side of the cigarette pack, and it required member states of the European Union to impose on manufacturers and suppliers of tobacco products, To submit a list of the contents and their quantities used, With the brand name and type, and prohibiting the use of any phrases, designations, trademarks, pictorial symbols, or any other symbols on the cover of the tobacco package that suggest that the product is less harmful than others.

## 3.1.1 Analysis of the national laws of some leading countries in the tobacco industry and how they affect industrial practices.

Regulation of tobacco products only began to be part of the scope of activities of the Harmonized System in Brazil in 1999, with the establishment of the Brazilian Health Regulatory Agency (ANVISA, Portuguese abbreviation), through Law No. 9782. In Brazil, prevalence rates for traditional cigarettes were estimated at 15.35%, while rates for hookahs and e-cigarettes were 1.65% and 0.43%, respectively. Although hookah-type tobacco products are ancient, the incorporation of flavor additives is more recent, and has become popular in Brazil in the past decade (Bertoni et al., 2019).

The nicotine in tobacco is considered a highly addictive substance, and tobacco companies use additives to enable the smoker to extract nicotine from tobacco more easily, to speed up the absorption of nicotine, and to improve the process of delivering nicotine to the brain.

Sugars are found naturally in tobacco, but tobacco companies also add sugars to their products. Sugars make tobacco products more palatable by reducing the intensity of the tobacco taste, especially for first-time users, and they also make it easier to inhale smoke. For decades, tobacco manufacturers have manipulated the taste, smell, and even appearance of tobacco products themselves, to increase their appeal to target groups such as youth, women, and specific ethnic groups.<sup>8</sup>.

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<sup>&</sup>lt;sup>7</sup> European Directive No. 40for a year2014 special, Manufactures, offers and sells tobacco and related products.

<sup>&</sup>lt;sup>8</sup> Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Addictiveness and Attractiveness of Tobacco Additives, 2010.

Some countries have set maximum levels of tar and nicotine, but few have bothered to regulate the design of the product itself. This is an area where significant progress can be made. Some researchers say we should start setting standards so that the labels "mild" and "soft" mean the same thing for all brands<sup>9</sup>.

The main legislation applicable to machinery in Brazil is Regulatory Standard No. 12 (NR-12) entitled "Safety at Work in Machinery and Equipment" approved by Order No. 3241 of June 8, 1978 of the Department of Labor and updated by Order No. 293 of December 8, 2011 of the Department of Labor. Regulation NR-12 specifies the technical references, basic principles and protection measures to ensure the health and physical safety of workers, and also specifies the minimum requirements for the prevention of occupational accidents and diseases in the stages of design and use of machines and equipment of all types. As well as with regard to manufacturing, importing, marketing and other aspects. It also considers preventive measures such as: collective protection measures, administrative or work organization measures and personal protection measures (Nara et al., 2021).

TakesNR-12 also takes into account other forms of accident prevention such as worker training and the preparation and development of a security manual which must include safety statements relating to safety since assembly (Nara et al., 2021).

Brazil's potential as an exporter has attracted the attention of foreign tobacco companies. Improving quality and stable supplies are among the elementsa The main strategy to penetrate global markets and maintain a significant market share in them. Every effort is made to meet the requirements of global demand, not only in quality control, but also in environmental protection and other requirements (social clause). Analyzes of the level of residues and alkaloids have been carried out, and campaigns have been implemented to reduce foreign substances in tobacco. Companies have implemented traceability practices to identify farmers who have not yet adapted to "clean tobacco" requirements, and the "Future Now" program aims to eliminate child labor in tobacco cultivation and manufacturing. <sup>10</sup>.

"Good progress has been made in tobacco control in recent years, but time is no longer complacent," says Dr. Rüdiger Kretsch, Director of WHO's Department for Health Promotion. "I am amazed at the lengths to which the tobacco industry will go to make profits at the expense of countless people." We see that the moment a government believes it has won its battle against

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<sup>&</sup>lt;sup>9</sup> Rob Cunningham, presented by Jake EPP La Guerre du tabac. L'experience canadienne; Introduction by Judith Mackay, research center for international development, published by the research center for international development, 1997.

<sup>&</sup>lt;sup>10</sup> Trade in tobacco and cigarettes: <a href="https://www.fao.org/3/y4997e/y4997e0b.htm">https://www.fao.org/3/y4997e/y4997e0b.htm</a>

tobacco, the tobacco industry seizes the opportunity to manipulate health policies and sell its deadly products."

Despite all the attempts made by the largest tobacco production and industry companies in the world, to deny the reality of the harm caused by tobacco, the quality and safety standards of the tobacco industry remain just a commercial lie and evasion through which those with economic interests seek to cover and conceal the heinous crime against humanity, as tobacco It is a deadly toxin that is licensed to be produced and sold, in order to achieve financial profits at the expense of the world's health.

There are some countries that have imposed a ban on smoking products, in particular:

• Panama issued<sup>11</sup> and Ethiopia<sup>12</sup> and India, legislation to ban the sale of used products. Mexico and Turkey have passed legislation to ban the import of hydrotreated products. In at least 12 countries, smoked products are banned under existing laws either because they ban all new nicotine products (Australia, Brazil, Norway, Singapore) or because smoked products are covered by laws prohibiting "smokeless" tobacco (Finland, Malta, Sri Lanka). Or e-cigarettes (Brunei, Cambodia, Qatar, Thailand, Uganda).

Many countries have not specifically regulated these practices, and while some implement existing tobacco control laws, regulation is often not comprehensive. For example, in many European countries, smoked tobacco cigarettes and capsules are often classified as "smokeless" tobacco products and this affects how tobacco control policy measures are applied to smoked tobacco. • Carry containers HTP only contains a 30% textual health warning instead of the 65% pictorial health warning required on traditional cigarette packs.

• It does not need to be packaging HTP in plain packaging in France, the United Kingdom or Slovenia, as these countries only apply plain packaging to cigarettes and roll your tobacco<sup>13</sup>.

So-called heated tobacco products have emerged, and are considered the latest innovation in the world of the tobacco industry. They aim to maintain the addiction of existing users and attract a new segment of consumers, including young people, by marketing them as a "safe alternative" or "low-risk".

Tobacco manufacturers present these products as an alternative to traditional smoking, stressing that they do not involve the combustion process that causes the formation of harmful

Resolution n° 0953. Panama (2018). Available at: www.tobaccocontrollaws.org/ files/live/Panama/Panama%20-%20Res.%20 No.%200953%20of%202018.pdf. Accessed August 24, 2020

Food and Medicine Administration Proclamation No. 1112/2019. Ethiopia (2019). Available at: www.tobaccocontrollaws.org/files/live/Ethiopia/Ethiopia/20-%202019%20 Proclamation%20

<sup>&</sup>lt;sup>13</sup> HTP regulation\_en PDF (assets.tobaccofreekids.org)

substances in the smoke. Although marketed to current smokers, there is controversy over the ability of these products to appeal to non-smokers and young people, raising concerns about increasing rates of abuse among this important age group.

But we must be aware that this industry is no stranger to these companies' history of providing misleading information about the health risks of their products. In the past, we have seen similar marketing campaigns promoting "light" cigarettes that claim to be less harmful, despite the fact that these claims are false and have a negative impact on public health. In addition, the same approach is applied to the marketing of heated tobacco products, where companies use innovative and attractive methods to young people around the world, raising concerns about the increasing rate of use among this important age group.

Italy has been a signatory to the WHO Framework Convention on Tobacco Control since September 2008. Italy has extensive legislation on the consumption of tobacco products as well as provisions for Italian companies that sell tobacco. Italian companies selling tobacco products are not permitted to display any direct or indirect advertising for tobacco products. Tobacco manufacturers are also required to label and sell cigarettes in compliance with Legislative Decree No. 184<sup>14</sup>

The Italian law relating to tobacco products consists of several laws and legislation, among them:

- public health law: contains legislation regulating the use and distribution of tobacco products and setting restrictions and conditions on their sale and promotion;
- consumer protection law: provides consumers' rights regarding tobacco products and safety, quality and marketing requirements;
- laws related to taxes on tobacco: these laws determine the taxes and fees imposed on tobacco products and the methods of estimating and collecting them.
- EU Tobacco Legislation: Italy adheres to European tobacco legislation that ensures product safety and consumer protection;

Italian laws stipulate some strict obligations for tobacco importers and manufacturers: "Manufacturers and importers of new tobacco products must immediately notify the Italian health authorities and provide all scientific, technical, and other relevant information about these products. (Id. Article 20) Among other obligations, manufacturers and importers of ecigarettes and e-cigarette recharge liquid containers must notify the authorities of their intention

<sup>&</sup>lt;sup>14</sup>Selling Tobacco Products in Italy; https://lawyersitaly.eu/selling-tobacco-products-in-italy/

to introduce these products onto the Italian market and provide information about them in the same way required for importers of any other smoking products."

Smokeless tobacco products are also subject to new warning regulations, and their packaging must include this message: "This tobacco product is harmful to your health and causes dependence." (ID Article 13(1)) Herbal-based smoking products are also subject to strict restrictions on their manufacture and sale in Italy, and their packaging must include this warning: "The smoke of this product is harmful to your health." (ID Article 22 (1))<sup>15</sup>.

And in fact, Tobacco as a product can generally be classified as either an inherently dangerous product or a defective product. An inherently hazardous product is one that poses an immediate health risk, even when used as intended. For example, tobacco is usually classified as an inherently hazardous product because it contains chemicals that are considered directly harmful to health, such as nicotine, tar, and other carcinogens.

As for a defective product, it is those goods that have defects in their design, manufacture, or use, which make them unsafe for use. For example, sometimes certain substances are added to tobacco products to improve their taste or smell, but these substances can be defective if they increase health risks or make tobacco more addictive. In other words, tobacco is considered an inherently dangerous product due to the known health risks associated with it, while it can be defective when it contains design or manufacturing defects that make it a greater health risk than expected.

Many global legislations, many public health bodies and international organizations classify tobacco as a product dangerous to public health. For example, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) emphasize the harmful effects of tobacco use on human health and consider tobacco a major factor in non-communicable diseases and deaths in the world<sup>16</sup>.

Many legislative measures have been taken at the international and national levels to reduce tobacco consumption and its harmful effects, such as imposing taxes on it, restricting its advertising, implementing laws prohibiting smoking in public places, encouraging programs

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<sup>&</sup>lt;sup>15</sup> Library of congress <a href="https://www.loc.gov/item/global-legal-monitor/2016-02-02/italy-implementation-of-european-legi">https://www.loc.gov/item/global-legal-monitor/2016-02-02/italy-implementation-of-european-legi</a>

<sup>&</sup>lt;sup>16</sup> According to WHO figures, tobacco kills more than 8 million people every year, while more than 7 million of these deaths are due to direct tobacco use. Of these, about 1.2 million are non-smokers who have been exposed to passive smoking. More than 80 percent of the 1.3 billion tobacco users around the world live in low- and middle-income countries, and 12 percent of deaths in people over the age of 30 are caused by smoking, according to the same source. <a href="https://www.aa.com.tr/ar">https://www.aa.com.tr/ar</a>

aimed at smoking cessation, and developing warning instructions on product packaging. Tobacco has been shown to have harmful effects on health.

The Italian Competition Supervision Authority (AGCM) has imposed fines totaling €7 million on British American Tobacco (BAT) and Amazon for deceptive advertising of heated tobacco products. Specifically, BAT was fined €6 million, and Amazon €1 million. The AGCM stated that the advertisements for the Glo Hyper X2 and Glo Hyper Air products were misleading, failing to provide consumers with adequate information about the nicotine content and health risks associated with these products. According to the AGCM, "Glo Hyper X2 and Glo Hyper Air were not advertised in an honest and informative manner to consumers." The authority emphasized that the advertisements did not properly communicate two critical warnings: the health risks due to nicotine in the tobacco sticks used with the devices, and the restriction that these products are not intended for minors. The AGCM further asserted that this misleading behavior prompted consumers to purchase products that pose health risks and are prohibited for minors. Additionally, Amazon was implicated because it sells these products directly on its online platform and promotes the Glo Hyper X2 on Amazon.it¹7

### 4 LEGAL RESPONSIBILITIES OF COMPANIES AND INDIVIDUALS

Since the 1950s, the tobacco industry has been sued by individual plaintiffs. The first case was filed in 1954 when Ira Lowe, a factory worker in St. Louis, "filed a products liability suit against the tobacco industry." Between 1954 and 1994, there were 800 lawsuits filed against the tobacco industry. During this period, the legal strategies of tobacco companies were very successful. Their legal tactics were two-fold:

- the tobacco industry has claimed that there is scientific debate about the dangers of smoking, and that although much research has been conducted, there is no conclusive evidence yet of a causal relationship between smoking and cancer or respiratory disease.
   If there is no causal relationship, then tobacco companies have done little to do;
- 2. The tobacco company's legal counsel argued that the plaintiffs knew the dangers of smoking and therefore accepted to put their health at risk when they started smoking. Both strategies were designed to remove liability from tobacco companies. During this

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<sup>&</sup>lt;sup>17</sup> Euronews:https://www.euronews.com/business/2024/02/14/italian-watchdog-turns-heat-up-on-bat-an

entire period, only two cases resulted in a ruling in favor of the plaintiffs, and both were overturned on appeal. Neither case resulted in damages for the plaintiffs<sup>18</sup>.

Numerous documents, some dating back to the early 1950s, reveal in detail how tobacco companies denied and covered up clear evidence of the danger of their products, including evidence from their laboratories. It revealed how the tobacco industry has conducted its own research on animals showing, for example, the carcinogenic effects of tobacco.

## 4.1 LEGAL RESPONSIBILITIES OF PRODUCERS, MANUFACTURERS AND DISTRIBUTORS IN THE TOBACCO INDUSTRY

Civil law considers civil liability a basis for achieving justice in cases of damage and accountability when it comes to certain products. In this context, when the elements of error, harm, and the causal relationship between error and harm are present, the question arises about the extent to which tobacco companies bear legal responsibility for the harm that their products cause to consumers. This debate reflects a tension between the consumer's right to protection and the legal protection enjoyed by tobacco companies.

If we look at existing legislation, we find that tobacco products enjoy legal advantages that protect them from illicit marketing and fraud. However, this does not mean that they are not accountable. Although tobacco products may comply with legal standards, consumers harmed by their use can file legal claims to seek compensation for the damages they have incurred.

These matters raise questions about fairness and balance between the interests of consumers and manufacturers. The affected consumer is always in need of protection from harmful commercial experiences, even if they are compliant with the laws. This reflects the basic idea of civil law, which aims to provide justice and protection to individuals against any unacceptable commercial abuses, regardless of their legality.

At the end of 1996, Richard Guerlain, who suffers from three types of lung and tongue cancer, filed a lawsuit against the French manufacturer on December 17. 1996 on charges of "continuous and gross failure to inform smokers of the dangers of expensive cigarettes, whose addictive and carcinogenic properties are linked to the serious material and moral damage they have suffered." Invoking the strict liability of the French manufacturer, the plaintiff and his family demand the sum of 2,668,090 francs in compensation for the damages suffered. Ten days later, the family of Susan Berger, who died of lung cancer, filed a lawsuit against the company SEITA

<sup>&</sup>lt;sup>18</sup> Tobacco Litigation; <a href="https://lawexplores.com/tobacco-litigation/">https://lawexplores.com/tobacco-litigation/</a>

"with the aim of forcing it to inform the public about the dangers of addiction and the serious dangers of its products." It seeks compensation in the amount of 1,158,499 francs<sup>19</sup>.

The company has filed Japan Tobacco International (JTI) filed a lawsuit against the Italian Customs and Monopolies Agency (ADM) following ADM's order to withdraw the "Camel Activate" and "Winston Expand" brands from the market. ADM found that the cigarettes contained menthol in violation of the Flavor Labeling Prohibition Act. JTI said ADM had not complied with the approved method for determining flavour characterization, as set out in a 2021 EU Commission decision<sup>20</sup>.

Philip Morris filed suit against the Federal Republic of Germany, claiming that its new tobacco product "Heat Stick, under the trade name "HEETS," is incorrectly labeled as a "smoking tobacco product." The plaintiff claimed that HEETS is a "smokeless tobacco product" on the basis that the combustion process does not occur during consumption as it generates vapor instead of smoke. The court explained that the distinction between a "smoking tobacco product" and a "smokeless tobacco product" depends solely on whether the tobacco product is consumed by a combustion process or not; It is not important whether smoke occurs when the tobacco product is consumed. The court found that the plaintiff's tobacco product was heated in a controlled manner without the tobacco igniting and therefore there was no combustion process. The court ruled that a tobacco product consumed in this way would be classified as a "smokeless tobacco product."<sup>21</sup>.

<sup>&</sup>lt;sup>19</sup> Isabelle Desbarats; Read more about the victims' direct tabagism; Rescue Dalloz 1998 p.167

 $<sup>^{20}</sup>$  No. 12091/2022 REGISTER OF COLLEGIATE COURT MEASURES No. 02897/2022 REGISTER OF PROCEEDINGS

<sup>&</sup>lt;sup>21</sup> Philip Morris GmbH v. Federal Republic of Germany, 4A 23/19, Administrative Court of Braunschweig (2021).

### **5 PENALTIES AND LEGAL CONSEQUENCES**

5.1 ANALYSIS OF PENALTIES FOR VIOLATIONS OF QUALITY AND SAFETY LAWS IN THE TOBACCO INDUSTRY.

As for Italian legislation, it was stated in the legislative decree<sup>22</sup>Issued on January 12, 2016, No. 6, in Chapter Four: Penal provisions in Article 25, which includes penalties for violating the articles regulating the dealing in tobacco, such as violating the provisions contained in each of:

- 1. part two: tobacco products, section one: ingredients and emissions, section two: labeling and packaging;
- 2. chapter three: electronic cigarettes and herbal smoking products and measures to protect minors section one: electronic cigarettes and herbal smoking products.

By reading the punitive texts in the aforementioned Italian legislation, it is noted that the penalties are of a financial administrative nature and include financial fines, and they do not qualify violation of the texts contained in the aforementioned decree as a criminal violation.

Under French law, violations of tobacco regulations are punishable by a fine of 100,000 euros. Repeated violations are punishable by a fine of 200,000 euros. In the event of a repeat violation, the court may impose a ban on the sale of products that were used in the illegal operation for a period of less than or equal to five years.<sup>23</sup>

### 5.2 CRIMINAL LIABILITY OF TOBACCO MANUFACTURERS

Corporate criminal liability rules constitute a legal framework that sets out how companies are held liable for crimes and illegal acts committed in their name or for their benefit. These rules aim to ensure that companies are held accountable for any illegal behavior resulting from the actions or negligence of their employees, which enhances transparency and accountability in the commercial sector.

of content regulation.

<sup>&</sup>lt;sup>22</sup> Implementation of Directive 2014/40/EU on streamlining the legislative, regulatory and administrative provisions of the member states regarding the processing, presentation and sale of tobacco products and related products, which replaces Directive 2001/37/EC. (16G00009). (Official Gazette No. 13 of January 18, 2016)
<sup>23</sup> The law is consistent with Art. 9 and 10 of the FCTC Partial Guidelines as they impose penalties for violations

### 5.2.1 Rules of criminal liability for commercial companies

According to the trend of current legal jurisprudence, corporate crimes fall within business crimes, which are dealt with by the business criminal law, which focuses mainly on crimes that have a direct or indirect relationship to business<sup>24</sup>.

Those who commit these crimes are often technical professionals, such as auditors or specialists, who occupy positions of authority and responsibility within their roles. A legal entity bound by private law cannot be held directly culpable for criminal acts. Instead, the crimes committed by such entities are typically executed through natural persons, who act on behalf of the company, most frequently the legal representatives. Dual accountability may be applied to both the company and its legal representatives under certain legal conditions."

Given that financial penalties can be imposed on companies under various legal systems, the specific penalties applied can differ based on the nature of the crimes committed and the applicable legal framework. Potential financial penalties may be:

- **financial fines**: imposed on companies as part of the punishment for committing violations, so the value of the fine is determined based on the type of crime, the size of the company, and the potential impact on the economy;
- **financial compensation:** companies may be required to pay compensation to affected individuals or entities, and the value of compensation is determined based on the damages incurred by those affected;
- **confiscation of illegal profits**: in some cases, profits made by a company from illegal activities can be confiscated;
- cancellation of commercial licenses and registrations: a company's licenses can be withdrawn or its registration canceled if serious crimes are committed.

As for attributing criminal acts to companies, the general rule considers the company criminally responsible if one of its employees or agents commits a crime while performing their work and within the scope of their authority. This includes acts committed to achieve a benefit for the company, such as an employee in a company offering a bribe to obtain a contract. Here the company can be held accountable. Criminal liability for the act committed by the employee.

The penalties imposed against legal companies that have a legal personality aim to ensure compliance with laws and regulations, and protect the rights of consumers. These

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<sup>&</sup>lt;sup>24</sup> Tayeb Belloula, Introduction to social affairs and commercial enterprises, British editions, Algeria, 2011, p10.

penalties vary according to the type of violation committed, including financial penalties, administrative penalties, criminal penalties, and complementary penalties.

**Financial penalties**: These represent financial fines imposed on companies that commit legal violations, such as violations of consumer protection laws or environmental regulations. The value of the fine is determined based on the seriousness and impact of the violation<sup>25</sup>.

**Administrative penalties:** It means temporary or permanent suspension of the license, so that the authorities can decide to suspend the company's license to practice a specific activity for a specific period or permanently in the event of committing serious violations, as withdrawing licenses represents a decisive measure to ensure that violations are not repeated.<sup>26</sup>.

**Criminal penalties**: It may sometimes happen that companies bear criminal responsibility for their actions, by imposing penalties on them. These penalties may include imposing penal fines or in some rare cases imprisonment for executive officials, so that corporate criminal liability enhances legal compliance and forces companies to adopt Stricter policies<sup>27</sup>.

**Supplementary penalties**: It consists of publishing the rulings. The company may be required to publish the court ruling or the regulatory body's decision publicly as a means of raising public awareness and deterring other companies from committing similar violations, as publishing the rulings enhances transparency and acts as a social punishment<sup>28</sup>.

### **5.2.2** Criminal liability of tobacco producing companies

The recent suggestion that tobacco companies may face criminal liability for their actions represents a significant development, and has already been taken into consideration by the drafters of the Framework Convention on Tobacco Control. In cases against the tobacco industry, parties have encouraged the use of their laws dealing with criminal liability under Article 19 of the Convention. This Article stipulates that Parties shall consider taking legislative

Intern. Journal of Profess. Bus. Review. | Miami, v. 9 | n. 7 | p. 01-27 | e04823 | 2024

<sup>&</sup>lt;sup>25</sup> A study issued by the Organization for Economic Cooperation and Development (OECD) on "Imposing fines on companies" (OECD, 2016) at the link: <a href="https://www.ccacoalition.org/ar/partners/organisation-economic-cooperation-and-development-oecd">https://www.ccacoalition.org/ar/partners/organisation-economic-cooperation-and-development-oecd</a>, accessed on: 09/28/2023.

World Bank report entitled "Improving the regulatory framework for companies" (World Bank, 2018) at the link: <a href="https://documents1.worldbank.org/curated/en/510621538160434570/pdf/The-World-Bank-Annual-Report-2018.pdf">https://documents1.worldbank.org/curated/en/510621538160434570/pdf/The-World-Bank-Annual-Report-2018.pdf</a>, accessed on: 09/28/2023.

<sup>&</sup>lt;sup>27</sup> A report issued by the American Law Society (American Bar Association, 2020) at the link: <a href="https://www.americanbar.org/content/dam/aba/administrative/news/2020/07/potlp2020.pdf">https://www.americanbar.org/content/dam/aba/administrative/news/2020/07/potlp2020.pdf</a>, accessed on: 09/28/2023.

<sup>&</sup>lt;sup>28</sup> European Commission report on "Transparency in Sanctions" (European Commission, 2019), at the link: <a href="https://op.europa.eu/webpub/com/general-report-2019/en/">https://op.europa.eu/webpub/com/general-report-2019/en/</a>, accessed on: 09/28/2023.

action or strengthening their existing laws, where necessary, to address the issue of criminal and civil liability, including compensation, as appropriate.

The criminal liability of tobacco-producing companies comes from several reasons, especially in light of the accusations against these companies because of the harm that tobacco causes to people's health and the danger they may be exposed to due to their addiction to using it, which led them to demand the necessity of prosecuting the manufacturers and describing them as criminals.

In this context, we can point to one of the cases in which activists from the Netherlands called on the public prosecutor to file charges against the four major tobacco manufacturing companies in the Netherlands for deliberately making smokers more addicted to smoking cigarettes by adding hundreds of substances. They accused these companies of attempted murder. Manslaughter or deliberate attempts to cause serious damage to the body, harm to health, and forgery of documents<sup>29</sup>.

The decision by the Attorney General to reject this complaint was seen as a setback for public health efforts worldwide, especially as multiple partners are currently working to bring criminal charges against tobacco industry companies in various courts, including the United States. In response, the tobacco industry in America has attempted to shift responsibility onto smokers, claiming they were aware of the dangers of smoking. However, all cases filed in American courts against smokers have thus far failed.

Tobacco production companies bear criminal liability for the harms of smoking through several legal aspects, including fraud, conspiracy to deceive the public, and violations of laws related to public health:

### 1. Fraud and conspiracy to deceive the public:

In this context, we are exposed to the case of United States v. Philip Morris (1999-2006), which was one of the most prominent cases in which major tobacco companies were accused of fraud and conspiracy to deceive the public about the dangers of smoking. The US federal government accused tobacco companies of clearly knowing the health harms caused by smoking. Smoking, but it deliberately concealed this information from the public and advertised its products in misleading ways. Accordingly, in 2006, the judge ruled that the tobacco companies were guilty and ordered them to implement public awareness campaigns about the dangers of smoking and to stop using misleading terms such as "light" and "low-tar." 30.

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<sup>&</sup>lt;sup>29</sup> Are the world's tobacco manufacturers being tried as criminals? An article published on the Al Jazeera Net website, dated: 02/27/2018, at the link: <a href="https://www.aljazeera.net/health/2018/2/27/">https://www.aljazeera.net/health/2018/2/27/</a>, accessed on: 07/07/2023.

<sup>&</sup>lt;sup>30</sup>Department of Justice, (https://www.justice.gov/archive/civil/cases/tobacco2/, 08/21/2018.

### 2. Greater Tobacco Agreement Settlement (1998):

The Master Settlement Agreement was a settlement between tobacco companies and 46 American states. The details of the case are that the United States sued tobacco companies to recover healthcare costs related to smoking-related illnesses, claiming the companies marketed their products deceptively and knowingly of their health risks. The lawsuit resulted in tobacco companies agreeing to pay over \$200 billion over 25 years, in addition to funding anti-tobacco programs and changing their marketing practices.<sup>31</sup>.

### 3. Smuggling and tax evasion:

This is exemplified by the EU Investigation into Tobacco Smuggling Activities (2004), where the European Commission investigated allegations of cigarette smuggling by companies such as Philip Morris and JTI to avoid paying taxes, and the investigations resulted in large financial settlements, with Philip Morris paying \$1.25 billion to the European Union as part of a settlement aimed at reducing smuggling and improving shipment control.<sup>32</sup>.

It should be noted that in 2019, the US Food and Drug Administration authorized the marketing of modified-risk tobacco products. (MRTP) to encourage switching from smoking to smoke-free tobacco products with the aim of reducing tobacco-related health risks, and thus helping prevent youth access to traditional cigarettes and other tobacco products. Scientific evidence, including long-term epidemiological studies, currently indicates that Use of special, smoke-free tobacco products poses a lower risk of mouth and lung cancer, heart disease, stroke, pneumonia, and chronic bronchitis than traditional cigarette smoking.<sup>33</sup>

### 5.2.3 Penalties related to violations of quality and safety laws in the tobacco industry

In French law, violations of tobacco regulations are treated very seriously, and the penalties imposed include large fines to ensure compliance with the laws, so that ArticleL3512-2 of the French Public Health Code A fine of €100,000 for violators of tobacco regulation, such as violations related to advertising or selling tobacco to minors. If the violation is repeated, the fine rises to 200,000 euros. These large fines aim to deter violators and ensure compliance with the laws to protect public health. In addition to financial fines, the penalties can include other

 $<sup>^{31} \</sup> Public \ Health \ Law \ Center \ (\underline{https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/commercial-tobacco-control-litigation/master-settlement-agreement)$ 

<sup>&</sup>lt;sup>32</sup> European Commission, <a href="https://ec.europa.eu/commission/presscorner/detail/en/IP\_04\_882">https://ec.europa.eu/commission/presscorner/detail/en/IP\_04\_882</a>), 07/09/2004.

<sup>&</sup>lt;sup>33</sup> FDA grants first-ever modified risk orders to eight smokeless tobacco products, website: <a href="https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products">https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products</a>, 10/22/2019.

measures such as closing establishments in which violations are repeated, in order to further enhance compliance with the laws. effectiveness<sup>34</sup>.

In Italy, sanctions are imposed on various entities related to tobacco products. For example, manufacturers and importers who violate the ban on selling cigarettes in packs containing fewer than 20 cigarettes are punishable by fines ranging from €20,000 to €120,000<sup>35</sup>. In addition, sellers who sell tobacco products to minors are punishable by fines of up to 8,000 euros and withdrawal of their business license for 15 days<sup>36</sup>. Administrative penalties in Italy may include closing the shop for a temporary or permanent period, or withdrawing business licenses.

In the United States, there is a master settlement agreement known as a master settlement agreement "Tobacco Master Settlement Agreement" (MSA), signed in 1998 between four of the largest tobacco companies in the United States and attorneys for 46 states. It was agreed to pay a minimum amount of \$206 billion during the first 25 years of the agreement (Sloan, 2004, p. 356), Lost Penalties are imposed on companies producing tobacco products in the United States if they violate the requirements of the Food and Drug Administration The maximum fine for violating tobacco product requirements is \$19,192 for a single violation, and an enhanced penalty is also permitted for certain willful violations<sup>37</sup>.

Regulation of the tobacco industry in the United States is subject to numerous laws and regulations intended to protect the public's health, reduce tobacco consumption, and reduce tobacco-related health harms. One of the bodies responsible for regulating this sector is the US Food and Drug Administration (FDA).

### **6 CONCLUSION**

Tobacco production companies face significant challenges today due to criminal liability and severe legal penalties resulting from their deceptive practices, which cause substantial harm to public health. Through complex legal cases and massive financial settlements, governments and health organizations seek to hold these companies accountable and strengthen legislation to curb

<sup>&</sup>lt;sup>34</sup> Legifrance - November 2016-41 on January 26, 2016 to modernize our sanitary system.

<sup>&</sup>lt;sup>35</sup> Country/Jurisdiction ITALY, website: <a href="https://www.tobaccocontrollaws.org/legislation/italy/sales-restrictions/">https://www.tobaccocontrollaws.org/legislation/italy/sales-restrictions/</a> penalties

<sup>&</sup>lt;sup>36</sup> Law December 28, 2015, no. 221, and Legislative Decree January 12, 2016, no. 6, have established new rules, prohibitions, and sanctions regarding tobacco, most of which are effective starting from February 2, 2016.

<sup>37</sup>Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, website: <a href="https://">https://</a>

<sup>&</sup>lt;sup>37</sup>Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, website: <a href="https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products">https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products</a>, 01/05/2024.

the spread of harmful smoking practices. This reflects their ongoing commitment to public health protection and increasing awareness of tobacco-related harms.

Dealing with the civil and criminal responsibility of tobacco companies is integral to comprehensive efforts aimed at safeguarding public health and mitigating the societal impacts of tobacco product consumption. However, these efforts encounter significant challenges, as companies often argue that plaintiffs were aware of smoking risks beforehand and that their addiction was voluntary.

Legislative texts, whether national or international, often provide legal protections for tobacco manufacturers and frequently exempt them from liability, despite the severe health risks posed by tobacco addiction.

Key recommendations include imposing stringent restrictions on tobacco marketing practices and banning the use of misleading terms. There should be strict control over manufacturing and distribution processes to combat smuggling and tax evasion. Additionally, high taxes should be levied on tobacco products to reduce consumption, with revenues used to enhance public health services and support smoking cessation programs.

To strengthen these efforts, encouraging class action lawsuits allows large groups of affected plaintiffs to file a single claim, increasing the likelihood of success and reducing litigation costs. Furthermore, strict regulation of packaging should mandate uniform, unappealing packaging for tobacco products, prominently displaying health warnings and pictograms.

Moreover, governments should have the ability to sue tobacco companies to recover healthcare costs associated with smoking-related illnesses. Establishing international mechanisms to monitor compliance with tobacco control laws and evaluating the effectiveness of implemented policies is also crucial.

These innovative and proactive steps will contribute to enhancing tobacco control efforts and effectively safeguarding public health, making tangible progress towards addressing this global health crisis.

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