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AN OVERVIEW OF USE AND REGULATION OF ADDITIVES IN CIGARETTES

Marija Srbinoska[1*], Vesna Radojičić[2], Kiril Filiposki[1], Stefka Kirkova[3], Nermina Djulančić[4]

[1] Scientific Tobacco Institute-Prilep, Republic of Macedonia
[2]Faculty of Agriculture, Belgrade- Zemun, Republic of Serbia
[3] Tobacco and Tobacco Products Institute, Plovdiv, Republic of Bulgaria
[4]Faculty of Agriculture and Food Science, Sarajevo, Bosnia and Herzegovina
srbinoska.marija@yahoo.com

ABSTRACT

In many countries around the world, tobacco control measures are becoming stricter and its directly reflect on to manufacturing and consumption of cigarettes.

In 2012 new regulatory framework is required in which the cigarette manufacturer is obliged disclose all additives used in cigarette by brand. This should include the impact of additives on smoking behaviour, passive smoking, direct or indirect pharmacological influence and fire risks.

The regulatory should permit additives necessary for the manufacture and storage of cigarettes providing these are safe, but should challenge all additives that may influence smoking behaviour.

Although it is impossible to make a safe cigarette, it is reasonable to prevent use of flavourings and additives that are harmful and increases the addictiveness of cigarette.

The aim of this work was to classify types of additives used in cigarettes, examine their legal status and reasons for the use or ban.

Key words: cigarettes, additives, regulation, use, smoke, tobacco

ПРЕГЛЕД НА УПОТРЕБАТА И ЗАКОНСКАТА РЕГУЛИТИВА НА АДИТИВИ ЗА ЦИГАРИТЕ

Во многу земји низ целиот свет, мерки за контрола на тутунот стануваат се построги и директно се одразуваат на производството и потрошувачката на цигари. Во 2012 година потребно е да се донесе нова регулаторна рамка со која производителот на цигари е должен објави сите адитиви што се користат во одреден бренд на цигара. Објавата треба да го вклучува влијанието на адитивите врз зависност од пушење, пасивното пушење, директно или индиректно фармаколошко влијание и ризикот од запалување. Регулаторите треба да дозволат да се применуваат адитиви кои се неопходни за производство и складирање на цигари и да се осигураат дека тие се безбедни, но треба да ги отстранат сите адитиви кои може да предизвикаат на зависност од пушењето. Иако е невозможно да се направи безбедна цигара, разумно е да се спречи употребата на аромите и адитиви кои се штетни и ја зголемува зависноста од цигарите. Целта на овој труд е да се класифицираат видови на адитиви што се користат во цигарите, да ги испита нивниот правен статус и причините за употреба или забрана.

Клучни зборови: цигари, адитиви, регулатива, употреба, чад, тутун

INTRODUCTION

Cigarettes are industrial form of tobacco use with a rather complex design providing the consumer with a product of high and consistent quality. Design features encompass a wide range of variables such as tobacco type and blend, chemical processing and ingredients, and in addition, physical features such as paper, filter and ventilation (Browne, 1990; Norman, 1999; Wigand, 2006).

The definition for additives from the European Union (Directive 2001/37/EC,2001), is "*Any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks, and adhesives*".

The term "additive" means "*any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco*" (FDA, 2012)

In the present work the term additives is use for added substances or ingredients. Additives are generally understood to be substances added to the basic components, such as tobacco, paper, filter materials, inks and adhesives, to impart specific desirable properties on them and control the performance of the cigarettes while being smoked. They are intentionally added to cigarettes by the tobacco industry to modify flavour, regulate combustion, moisturise the smoke, preserve the cigarettes, and in some instances to act as solvents for other additives (Rabinoff, 2007)

Cigarette styles are characterized by their tobacco blend. There are two major styles of cigarettes worldwide: flue-cured cigarettes, which use very few additives, and traditional blended cigarettes, which use a number of additives. Flue-cured cigarettes contain only flue-cured tobacco and do not use flavor ingredients. These cigarettes are popular in most of the British Commonwealth (Australia, Canada, India, Malaysia, Pakistan, Nigeria, the U.K. and South Africa).

Traditional blended cigarettes utilize three different types of tobacco − flue-cured, burley, and oriental − that are blended together during the manufacturing process. Blended cigarettes are the most popular cigarettes in the United States, most of Europe, Latin America, Eastern Europe and many Asian countries. Various additives are combined into the shredded tobacco product mixtures, with humectants such as propylene glycol or glycerol, as well as flavouring products and enhancers such as cocoa solids, licorice, tobacco extracts, and various sugars, which are known collectively as "casings". The leaf tobacco will then be shredded, along with a specified amount of small laminate, expanded tobacco, blended and reconstituted leaf sheet, expanded and improved stems. A perfume-like flavour/fragrance, called the "topping" or "toppings", which is most often formulated by flavor companies, will then be blended into the tobacco mixture to improve the consistency in flavour and taste of the cigarettes associated with a certain brand name. Additionally, they replace lost flavours due to the repeated wetting and drying used in processing the tobacco. Finally the tobacco mixture will be filled into cigarettes tubes and packaged (Fisher, 1999, Георгиев С, 2002; Nikolić, 2004).

Beyond the core ingredients in cigarettes (tobacco leaf and paper), there is a list of at least 599 ingredients that are known to have been added to cigarette tobacco. This list of ingredients was submitted by the five major American tobacco companies during 1994 congressional hearings investigating the tobacco industry. The list contains a number of common flavoring agents, such as vanilla. It also includes hundreds of other chemicals approved for use in food products by the Food and Drug Administration (FDA).

The number of additives used may vary with anywhere from 30 to 150 different flavours being used for one brand (Manus, 1989). The tobacco industry claimed it had 1400 additives that could be put into cigarettes (Manus, 1989).

Additives can account for over ten percent of the total weight of a cigarette (Bates et al., 1999). The characteristics of each brand depend on the tobacco type and blend, how it is cured, the additives used and other technical characteristics of the cigarette. Ingredient mixtures differ between brands and even within a given brand because of country-specific preferences.

Many countries regulate tobacco product ingredients. Over 50 countries require tobacco manufacturers to report the ingredients used in their products to regulators. These countries include all of the European Union countries, Brazil, Mexico, Ukraine, Turkey, Israel and Thailand. Several countries, including Germany, the United Kingdom and France, also regulate the ingredients that are permitted for use in tobacco products.

The countries of south-eastern Europe, Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Macedonia, Montenegro, Romania and Serbia have recognized that they have significant public health, economic and social problems relating the lack of tobacco control.

More than 170 countries adopted in November 2010 at the conference of the World Health Organization (WHO) in Uruguay measures to control the use and sale of tobacco products, including those related to adding flavors in cigarettes. It has recommended that additives used to make cigarettes more appealing to new smokers should be restricted or banned. Recommendations from the Uruguay conference were to determine whether countries should forbid addition of all new additives and explicitly address the possibility of reducing the use of additives that make tobacco products more attractive and/or taste better. … (WHO, 2010).

A new regulatory framework is required these countries in which the manufacturer is obliged to submit information about additives. For each additive that the tobacco company used for cigarettes they manufacture and, for cigarettes that are imported, the company should submit information. There decided to be a full disclosure of ingredients, additives and smoke constituents by brand or only for "Characterizing flavours ".

For this reason, tobacco additives should be seen as a public health issue and an appropriate regulatory framework would require the tobacco companies to disclose used additives in countries of Balkan region.

Additives and tobacco industry

Increased knowledge about cigarette additives makes it clear that modern cigarettes are very different from cigarettes of the past. Bates et al. (1999) report that there are 600 tobacco additives allowed in the cigarettes, most of them were included in the manufacturing of cigarettes after 1970.

Chitanondh (2000) suggests that the need for additives arose with the development of filters and "low-tar" products in response to consumer demand for a reduction in health risks. Filters, low tar and nicotine alter flavour – the smoke becomes drier, losing much of its body. Taste yield is reduced and the descriptive analytical profile of the smoke flavour changes. A repeatedly described taste deficiency is that of a "dry mouth feeling".

The rise of additives in tobacco products is linked with the strategy to reduce tar yields. When health concerns related to smoking were first raised in the 1950s, cigarette manufacturers responded by introducing filtered cigarettes. Manufacturers competed with one another to reassure health conscious smokers with new, "healthier" products (Pollay and Dewhirst, 2000). By the early 1960s in the USA, some health groups expressed concern that these health claims were not backed by objective scientific data. In 1967, the Federal Trade Commission (FTC) in the USA began a program to test cigarettes for tar and nicotine yields in cigarette smoke (Peeler, 1996).

"Light" cigarettes were introduced on the market in the 1970s. Typical for light cigarettes is their high grade of ventilation. Due to the delivery of less tar, the impact and taste of the "diluted" smoke is also decreased. It is therefore probable that the light cigarettes were "enriched" by adding more substances, and in higher amounts, to compensate for reduced taste and impact. At the same time an extremely lax regulatory regime for additives has emerged (SCENIHR, 2010).

In 1984, the US Department of Health and Human Services began requiring tobacco companies to submit annually a confidential,

aggregated list of ingredients added to cigarettes manufactured in or imported into the United States.

There is evidence that the percentage of additives by weight may have increased in the 1990s, especially the use of sweeteners (Bates et al., 1999).

In 1994, National Public Radio reported on a number of these ingredients, which caused a public outcry. Subsequently, in that same year, the 6 major US tobacco companies made the list public. This was the only time the list was made public, and there is no current public list of tobacco additives (Rabinoff et al.,2007, Additive list, 1994).

Tobacco companies have devoted a significant amount of research and development to the use and inclusion of different additives in cigarettes (Bates et al., 2000; Lewis and Wackowski, 2006).

According to various tobacco company documents, many of these additives are used by manufacturers to influence the pharmacological effects of nicotine, make individual brands taste more appealing to smokers and mask the taste and immediate discomfort of smoke (Bates et al., 1999, Paschke et al., 2002, Pötschke-Langer M., 2012)

Other important reason for using additives is to give the cigarette a specific and standardised taste. A specific taste is important for the company to be competitive on the consumer market in view of the large variety of brands available. The specific taste of a certain product must be preserved (standardised) to compensate for the yearly variation of the natural tobacco, because consumers do not like to smoke a product that changes from year to year.

Additives and manufacturing process

Tobacco companies intentionally add additives to tobacco for several reasons including increasing the moisture-holding capacity, enhancing the taste of tobacco to make the product more desirable (e.g. sweeteners, flavourings, menthol), masking the smell and visibility of sidestream smoke, and decrease smoke irritability (Wigand, 2006, SCENIHR, 2010).

There are two distinct classes of additives, namely intentional and unintentional. Intentional additives encompass *all* chemicals, substances, complex botanical extracts, flavorings, ingredients, inks, gums, combustion modifiers, aesthetic, inorganic salts or functional chemicals, etc., that are deliberately added to a traditional tobacco product, that is either combusted or heated (Wigand, 2006).

Unintentional additives have not specific purpose but are by-products of the tobacco growing (fertilizers, pesticides, metals absorbed from the soil etc.), handling and manufacturing processes (conveyor belt fragments, oil from the machinery) (Wigand, 2006).

Also, additives may be natural or synthetic; they may include artificial tobacco substitutes, flavour extracts of tobacco and other plants, exogenous enzymes, powdered cocoa, and other synthetic flavouring substances.

Additives are defined as any ingredient or substance that is added, except water, during the course of manufacture of a tobacco product, including casings, humectants, flavours, and processing aids (Wigand, 2006).

Typical tobacco additives include:

Humectants are substances which increase the moisture-holding capacity of the tobacco. Preservatives include substances that protect the product from deterioration caused by microorganisms (Wayne and Connolly, 2002.).

Solvents are substances used to dissolve or dilute ingredients, without altering their function, in order to facilitate their handling and application.

Binders and strengtheners are substances that make it possible to maintain the physical state of the product. Fillers allow the product to keep the volume without contributing significantly to odor, taste or flavor.

In cigarettes, flavours may be added to tobacco, cigarette paper, the filter, in a plastic pellet placed in the filter or the foil wrapper, in an attempt to enhance the tobacco flavour, mask unpleasant odour, and deliver a pleasant cigarette-pack aroma. Internal industry documents reveal additional flavour technologies such as flavour micro encapsulation in the paper, carbon beads, and polymer-based flavour fibres inserted into the filter, flavoured tipping etc. (Nikolić, 2004, WHO, 2007, SCENIHR, 2010).

They may be used as casing ingredients or flavourings (sometimes referred to as top flavours). Casing ingredients are substances used to enhance the tobacco product sensory quality by balancing sensory attributes and developing certain required taste and flavour characteristics. Casing refers to the sauce composed of a variety of ingredients such as humectants, sugars, cocoa, liquorice and fruit extracts. They are usually applied to tobacco strips or leaf early in the primary processing scheme to tone down or mute the strength or harshness of tobacco smoke, improve processibility of tobacco and add deep flavour notes to the smoke. Being used early in the process, different casings can be applied to the various tobacco blends (e.g., burley, flue-cured, oriental, etc) (Brown, 1990, Fisher, 1999, Nikolić, 2004).

Flavorings (or top flavours) are substances used to impart a specific taste and flavor in a tobacco product. They are applied to the cut and processed tobacco prior to cigarette manufacture, usually in parts per million (ppm) quantities in a complex mixture in solution. Those tobacco blends that contain flavours and flavourings are usually held in a bin to allow for equilibration across the blend before it is passed to the making machine as the final blend. Flavorings are used to improve quality of smoke, impart a pleasant pack aroma and side stream aroma, and give the tobacco brand its unique sensory characteristics (Fisher, 1999, Nikolić, 2004).

The tobacco industry has pursued many non-conventional flavour technologies to address the goal of unique flavour delivery. For example, internal documents reveal that polymer pellet technology, using a flavoured filter pellet (polyethylene bead), was designed to provide controlled release of flavour for delivery to the smoker (Arzonico, 1989, Saintsing, 1992). Philip Morris also explored flavour release technology using carbon beads (Moore, 1994.) and various additives (i.e. cinnamaldehyde and gluco-vanillin) designed to flavour mainstream and sidestream smoke (Houminer, 1989) with a sweet, vanillin-type aroma. Additional flavour technologies described in tobacco industry documents include flavour microencapsulation in the paper, packaging technology, polymer-based flavour fibres inserted into the filter, and flavoured tipping (Saintsing, 1992, Douglas, 1989, Robinson, 1992.).

Menthol may be added at any of the following stages; spraying onto the final blend, through addition to the filter via a thread, or by application to the cigarette paper or the foil used to wrap the cigarettes. Due to the high level of volatility of menthol, different manufacturers have over the years developed a variety of methods for producing mentholated products that are as consistent as possible in terms of their finished product menthol levels (SCENIHR, 2010, Neck, 2010.).

"Flavoured tobacco product" means any tobacco product or any component part thereof that contains a constituent that imparts a characterizing flavour. "Characterizing flavour" means a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic, beverage, herb or spice; provided, however, that no tobacco product shall be determined to have a characterizing flavour solely because of the use of additives or flavourings or the provision of ingredient information… Non-characterizing flavours are licorice and cocoa (The Tobacco Control Legal Consortium, 2011).

Processing aids facilitate the manufacture of cigarettes, such as by making cured tobacco less brittle. These include several ammonia compounds, carbon dioxide and ethyl alcohol.

Ammonia compounds are added to some brands in order to increase the level of unprotonated nicotine in the smoke (Bates et al., 1999a).

Regulation

There are important efforts to regulate tobacco products, such as the World Health Organization's Framework Convention on Tobacco Control (FCTC) and the US Congress' consideration of legislation to give the Food and Drug Administration (FDA) regulatory authority over tobacco (WHO, 2003).

The Framework Convention on Tobacco Control (FCTC), to which 176 countries are currently parties, contains a number of key

demand-reducing strategies, such as tobacco taxation, education about health effects (including health warnings on packages), removal of misleading product descriptors, and support for cessation. As of August 30, 2012, 168 countries have signed and ratified or accepted the treaty. This is more than 85% of the world's population.

Nine countries have signed but not yet ratified the WHO FCTC: Argentina, Cuba, El Salvador, Ethiopia, Haiti, Morocco, Mozambique, Switzerland, and USA.

On the basis of public health protection, the Tobacco Products Directive (2001/37/EC) foresees measures on the manufacture, presentation and sale of tobacco products. It sets maximum limits for tar, nicotine and carbon monoxide yields of cigarettes and requires the industry to report on ingredients in tobacco products (Directive 2001/37/EC, 2001).

Siem (2000), has reported on the wide differences between the measures countries have taken in their efforts to regulate tobacco as a product. Until recently, the most relevant legal instruments to this issue - those to regulate consumer products and foodstuffs – have only exceptionally been used. He suggests that "the way is now open" for States to legislate their rights to verify the content of tobacco and smoke, to inspect production sites, limit the amount of certain ingredients, and approve additives. They can also request the declaration of certain additives, the purpose for their use and a toxicological evaluation.

Under Articles 9 and 10 of the FCTC, parties will be developing systems to regulate the contents, design and emissions of products and to require reporting on the same from manufacturers. To date, several countries currently have limits on tar and nicotine emissions (for example, European Union, Brazil, South Africa, Egypt) and others require regular reporting of tar and nicotine emissions (for example, Canada, United States, Hong Kong).

Article 6 of the Tobacco Products Directive 2001/37/EC requires that manufacturers and importers of tobacco products submit a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. It specifies the content of this list and requires that the list be accompanied by the toxicological data available to the manufacturer and importer.

In 2001, the European Parliament adopted Directive 2001/37/EC concerning the harmonization of the regulation of tobacco products in the member states of the European Union (Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products).

The production of tobacco and cigarettes and their consumption in European Union is influenced by the World Health Organization WHO through the EU health policy, based on the principles of Warszawa declaration and the EU strategy for tobacco control (ESTC-European Strategy for Tobacco Control). All this principles are harmonized with the Framework Convention for tobacco (FCTC), under guidance of the WHO, and signed by all European Union, and some countries in development.

Reporting requirements have been adopted in various jurisdictions including European Union, Canada, Brazil, Thailand and some state of the US. FDA has developed an electronic submission tool, eSubmitter, to streamline submission and receipt of the ingredient information required by sections 904(a)(1) and 904(c) of the act.

The European Commission's Practical Guide on "Reporting on tobacco product ingredients", issued on 31 May 2007, and specifies the reporting format, which is the basis for the EMTOC system. Additionally required information is collected solely for the purposes of data processing and communication (Practical Guide Reporting on tobacco product ingredients, 2007).

In Canada, for example, tobacco manufacturers must report the quantity of all ingredients used in the cigarette paper and filler, as well as the levels of specified chemical constituents in tobacco and mainstream and sidestream smoke emissions. On May 26 2009, Canada's Health Minister tabled Bill C-32, which would ban flavoured cigarillos, cigarettes and blunts (tobacco rolling papers), but exempt menthol as an additive (House of Commons of Canada, 2009).

In the United States, New Zealand, and Chile, tobacco manufacturers report a composite list of additives which may be present in any

tobacco product. New Zealand additionally requires manufacturers to provide the maximum levels of each additive present in various types of tobacco products, including cigarettes (Thomson, 2005).

Brazil's National Health Surveillance Agency (ANVISA) passed new regulations which ban the use of additives and flavorings in all tobacco products. The new regulations will ban the use of menthol, clove and ammonia among a long list of additional banned additives.

Moreover, the bill that would the United States Food and Drug Administration (FDA) to regulate tobacco, would ban flavoured cigarettes, but exempts menthol (Waxman, 2009).

Australia has been negotiating with Australian cigarette manufacturers for the disclosure of ingredients (Health Government of Australia. 2009). The sale of most confectionary-flavoured, confectionary-scented and fruit-flavoured or fruit-scented cigarettes is banned in ACT, New South Wales and South Australia.

The first report on the application of the Tobacco Products Directive 2001/37 EC indicated that in the EU different reporting formats are used for the submission of tobacco products ingredient and emission information. The data sets delivered by manufacturers and importers to Member States are often incomplete. The first report therefore suggested that the Commission develops harmonised data collection methods that are based on a common EU format and improved definitions (Directive report, 2005).

In a Germany and the UK, the government publishes lists of ingredients that are permitted or prohibited for use in tobacco. The UK sets a maximum limit for each additive based on percentage added by weight of tobacco (Geiss and Kotzias, 2007).

Germany prohibits use of a number of additives. In both cases, disclosure of additives is not required from manufacturers, although the UK House of Commons Health Committee recently required the companies to submit additives by brand to them. These were then published in full, by brand, on the Health Committee's website, although flavourings are not broken down into their constituent parts (WHO Monograph, 2000).

The Tobacco Manufacturers Association of Denmark disclosed in July 2000 a list of 37 additives used in cigarettes on the Danish market which also included the additives' purpose of use (WHO Monograph, 2000).

Philip Morris and Imperial Tobacco have voluntarily submitted their own composite additive lists. However, a look at the websites of the larger cigarette manufacturers show, that, in a given brand, typically less than 10 different tobacco ingredients are used at concentrations higher than 0.1% (PMI, 2012).

In addition to the purposes listed above, this publication also included several further types of ingredients, including burn additives, plasticizers, preservatives, adhesives, dyes, and processing aids. Several of these types of ingredients are placed into or form part of the cigarette filter, where smoker exposure, if there is any, would be restricted to the ingredients in their natural form (i.e., not subject to changes incurred during the burning of tobacco) (Dempsey et al., 2011).

In the Republic of Macedonia, according to the Law on Tobacco and Tobacco Products "Manufacturers and importers of tobacco products at the request of the Ministry of Health are required to submit the data on the additives used in the manufacture of tobacco products and tobacco smoke onto the prescribed form. The form and content of the form referred to in paragraph 4 of this Article, its delivery and use of data by the Minister of Health (Law on Tobacco and Tobacco Products). Lists of permitted and non-permitted additives are given in the Official Gazette of the Republic of Macedonia No.56, 2007 (Lists of permitted and non-permitted additives, 2007).

The requirements under section 4 apply to each "tobacco product manufacturer or importer." We interpret this to mean that domestic manufacturers are to submit the required additive information for products they manufacture and, for tobacco products that are imported, the required ingredient information is to be submitted by either the foreign manufacturer or the importer of the product. This includes any regulated tobacco product, whether for sale to consumers or for further manufacturing. But this legal provision is not fully implemented.

DISSCUSION

Increased knowledge about cigarette additives makes it clear that modern cigarettes are very different from cigarettes of the past. Cigarettes are produced by an industrial process which, through a number of steps in handling the tobacco and by the use of additives, is tailoring the product to satisfy the user (Siem, 2000).

Tobacco companies have devoted a significant amount of research and development to the use and inclusion of additives in cigarettes and the industry has acknowledged using 600 different cigarette additives. According to various tobacco company documents, many of these additives are used to improve taste and decrease harshness (Rabinoff, 2007).

Tobacco companies claims that all of the additives used in the manufacture of cigarettes and other tobacco products are approved for use by either by the FDA GRAS list or the Flavor and Extract Manufacturers Association (FEMA). But, although a tobacco ingredients and additives may indeed appear on the GRAS list, this does not guarantee that this ingredient is safe. The main problem with the GRAS argument is that the ingredients on the GRAS list were never intended to be burned or inhaled.

Justification for the use of tobacco additives cannot be based solely on their approved use in food since, potentially, they could decompose into other substances during tobacco combustion in the smoking process. An assessment should include consideration of possible thermal decomposition of the ingredients, their effects on smoke chemistry and potential impact on smoke toxicity

The overall outcomes of investigations of manufacturers were the finding that tobacco ingredients - at levels typically used in tobacco products - have very limited influence on smoke chemistry. Three major reviews were published in 2002 that examined studies on the chemical and biological effects of tobacco ingredients on smoke properties conducted over the last 50 years (Paschke et al., 2002; Rodgman, 2002 a, b).

Rodgman conclusions were similar to those of Paschke et al., namely that ingredients added to tobacco during commercial cigarette manufacture in the U.S.A. do not increase the toxicity of cigarette smoke.

Also during 2002, Carmines and co-workers published a series of four papers that described a comprehensive study on the evaluation of 333 ingredients used in Philip Morris products. This study included smoke chemistry, in vitro genotoxicity and cytotoxicity, and animal sub-chronic inhalation toxicity (Carmines, 2002; Rustemeier et al., 2002; Roemer et al., 2002; Vanscheeuwijck et al., 2002). Taking into account all the smoke chemistry and biological data, they concluded that the addition of the ingredients to tobacco did not increase the toxicity of the smoke.

Some additives have been used to increase the apparent impact and addictiveness of cigarettes, it may also be possible to reduce the addictiveness of cigarettes without eliminating the nicotine by either prohibiting certain additives or requiring them (Henningfield et al., 1998). Increasing smoke delivery of nicotine has also been achieved using chemical additives such as nicotine maleate (Robertson, 2000). Chitanondh (2000) describes the several known carcinogenic or otherwise dangerous additives currently known to be present in cigarettes.

In 2002 Seeman et al. published a comprehensive review of the formation of acetaldehyde in mainstream cigarette smoke and its bioavailability in the smoker (Seeman et al., 2002).

Because of the importance of sugars as tobacco ingredients in American-blend cigarettes, many studies have been performed in order to understand any potential toxicological impact of sugars use (Baker, 2006; Talhout et al., 2006; Roemer et al., 2012). All of these studies used tobacco blends representative of American-blend cigarettes to produce research cigarettes that were cased with various levels of the respective sugar ingredient. It was found that sugars and polysaccharides materials were associated with increased formaldehyde yields. Cahours et al. (2012) supports the conclusion that structural material in the tobacco plant is the main source of acetaldehyde in mainstream smoke after combustion during cigarette smoking.

There is speculation that added ingredients which may be Generally Regarded as Safe (GRAS) from studies on usage in foods, may increase the toxicity of the smoke by forming ‘‘new’’ smoke constituents (or increase the concentrations of existing constituents)

during pyrolysis and combustion (Thielmann and Potschke-Langer, 2005).

In the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report published in 2010, attractiveness with regard to tobacco products is defined as the stimulation to use a tobacco product. The attractiveness of tobacco products may be increased by a number of additives. Specific additives can mask the bitter taste, improve the flavour and reduce the irritation of inhaled smoke. Examples of flavouring substances include sugars, benzaldehyde, maltol, menthol and vanillin. Altogether, these additives have the potential to enhance the attractiveness of cigarettes. The use of a combination of ingredients includes the investigation of any potential interactions among the ingredients, while the use of single ingredients allows greater exaggeration of the application levels of the particular ingredient beyond use levels found in commercial cigarettes (Connolly et al., 2000, SCENIHR 2010). Some additives, although not directly toxic in themselves, may nevertheless increase tobacco-related harm by making cigarettes more palatable, attractive, or addictive to consumers (Bates et al., 1999 a).

Tobacco industry has acknowledged that the addition of alkali such as ammonia to increase smoke pH increases the availability of "free" or "unbound" nicotine and thereby increases the nicotine addictiveness for given nicotine content (Henningfield et al., 2004).

The intended purpose of additives needs to be fully understood. If the purpose is to facilitate extra smoking or to increase the addictiveness of the product, it hardly matters whether the additive itself is toxic or benign.

European Commission Health and Consumer Protection Directorate (2010) recommended that ingredients have usually been evaluated as design principles rather than repeatedly for each product. For principle-based testing, ingredients may be applied to research cigarettes, either individually or in combination, in a manufacturing process which corresponds to that of commercial cigarettes.

The European Commission has announced that it is considering legislation concerning further restrictions on cigarette tar and nicotine yields, as well as new provisions to regulate additives and the labelling of the tobacco products.

The third meeting of the working group on economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the WHO FCTC was held in Geneva from 14 to 16 February 2012. The meeting was attended by Key Facilitators and Partners of the group. Participants also included representatives of WHO, the International Labour Organization, the Food and Agriculture Organization of the United Nations and the United Nations Environment Programme, as well as representatives of nongovernmental organizations accredited as observers to the Conference of the Parties (COP) and invited experts. The group discussed the draft policy options and recommendations presented by the Key Facilitators, including issues concerning standardization of terms and a methodological framework, for submission to COP5.

The fifth session of the Conference of the Parties (COP5) will be held from 12 to 17 November 2012 at COEX Convention Centre in Seoul, Republic of Korea.

The Parties to the Framework Convention on Tobacco Control, which also include Macedonia, Serbia and Bosnia and Herzegovina, have reached an agreement on the introduction of assistance programs for smoking cessation in national health systems and support campaigns to raise awareness of the population, according to a WHO statement.

Regulation of additives will be an important issue for research and potential future regulatory attention.

CONCLUSION

Cigarettes are manufactured by an industrial process which, through a number of steps in handling the tobacco, non-tobacco materials, and by the use of additives, is tailoring the product to satisfy the user. American style of blended tobacco cigarettes is increasing. For example, when worldwide cigarette demand was growing only 1% per year, the demand for American style products was projected to grow 3% annually (EUROMONITOR, 2012).

Comprehensive disclosure of smoke constituents and additives would improve

consumer information, and removal of misleading branding and labelling of tobacco products.

The regulators should know which additives are in which brands and only permit them in brands where it could be proven that they would facilitate a public health gain. All additives should be covered by the regulations, including those added to non-tobacco materials (cigarette papers, filters, filter wrappers, and overwrappers). For particular cigarette, manufacturer should disclose the contents of all additives at regular intervals.

Proposed elements of tobacco product regulation

- Manufacturers should be required to disclose all additives (intentional and unintended) used in cigarettes, by brand, to a regulator.
- Some information should not be confidential, but made available to the public through publications, the Internet or on request from the regulator.
- There may be some additives that should be listed as ingredients on tobacco product packaging.
- Regulatory framework should permit additives necessary for the manufacture and storage of cigarettes providing these are safe, but should challenge all additives that may influence smoking behavior.

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