

# TOBACCO PRODUCT REGULATION

## Basic Handbook



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**TOBACCO PRODUCT REGULATION**

# **Basic Handbook**



Tobacco product regulation: basic handbook

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## PREFACE

Although tobacco use is a major public health problem, tobacco products are one of the few openly available consumer products that are virtually unregulated in many countries for contents and emissions. In recent years, health authorities have become increasingly interested in the potential of tobacco product regulation to reduce the morbidity and mortality associated with tobacco use. However, barriers to implementing appropriate regulation include limited understanding of common approaches or best practices, and a lack of adequate resources and/or technical capacity.

The importance of tobacco products regulation is reflected in World Health Organization Framework Convention on Tobacco Control (WHO FCTC) (1). Article 9 of the WHO FCTC defines obligations for Parties with respect to the regulation of the contents and emissions of tobacco products, while Article 10 deals with the regulation of disclosure of information on the contents and emissions of tobacco products. Disclosure of product information takes two forms:

- the disclosure of information by manufacturers to health authorities; and
- the disclosure of information from health authorities to the public.

In 2006, the first session of the Conference of the Parties (COP1) to the WHO FCTC established a working group to elaborate guidelines and recommendations for the implementation of Article 9 (2). The second session extended the mandate of the working group to consider guidelines for Article 10 and encouraged WHO's Tobacco Free Initiative (TFI) to continue its work on tobacco product regulation (3).

Partial Guidelines on the implementation of Articles 9 and 10 (4) were adopted at the fourth session of the COP in 2010, and further additions were adopted at COP5 and COP7. The working group was requested to continue to elaborate guidelines in a step-by-step process, and to submit further draft guidelines to future sessions of the COP for consideration.

The Partial Guidelines currently contain recommendations for regulations to reduce the attractiveness of tobacco products. They also contain guidance with respect to the testing and measuring of the contents of tobacco products. Recommendations to reduce the addictiveness and toxicity of tobacco products may be adopted at a later stage. It is important to note that, contrary to claims by the tobacco industry, these guidelines are in effect. The regulatory measures in the Partial Guidelines are to be treated as minimum standards and do not prevent Parties from adopting more extensive measures, in line with WHO FCTC Article 2 (1) which provides that "Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law".

WHO has continually provided support to its Member States in regulating tobacco products and in developing laboratory capacity through a series of advisory notes and other resources on issues such as menthol and nicotine. In addition to this handbook, WHO published a guide on building laboratory testing capacity in 2018 (5) to guide countries interested in developing or accessing tobacco product testing capacity to support their regulatory authority.

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# ACRONYMS USED IN THIS PUBLICATION

**COP** – Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control

**COTPA** – Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act

**CNS** – central nervous system

**ENDS** – electronic nicotine delivery systems

**ENNDS** – electronic non-nicotine delivery systems

**EU** – European Union

**EU CEG** – EU Common Entry Gate

**GCRC** – German Cancer Research Centre

**GTRF** – Global Tobacco Regulators Forum

**HTP** – heated tobacco product

**LIC** – low-income country

**MRTP** – modified risk tobacco product

**RIP** – reduced ignition propensity

**TBT Agreement** – Agreement on Technical Barriers to Trade

**TNCO** – tar, nicotine and carbon monoxide

**TPD1** – European Union’s former Tobacco Products Directive (2001/37/EC)

**TPD2** – European Union’s current Tobacco Products Directive (2014/40/EU)

**TRP** – tobacco and related products

**U.S. FDA** – United States Food and Drug Administration

**WHO** – World Health Organization

**WHO CC** – WHO Collaborating Centre

**WHO FCTC** – WHO Framework Convention on Tobacco Control

**WHO TobLabNet** – WHO Tobacco Laboratory Network

**WHO TobReg** – WHO Study Group on Tobacco Product Regulation

**WTO** – World Trade Organization

## Chapter 1.

# THE BASICS OF TOBACCO PRODUCT REGULATION

Parties to WHO Framework Convention on Tobacco Control (WHO FCTC) and other Member States have requested WHO to provide authoritative guidance on tobacco product regulation, especially in line with the requirements of Articles 9 and 10. This handbook examines the building blocks of tobacco product regulation and identifies approaches, challenges, and broad guidance for regulation. It provides a basic reference document for non-scientist regulators in any country and serves as a tool for health authorities and other interested parties seeking resources and planning on how to monitor, evaluate, and regulate tobacco products. However, this handbook is not designed to replace or completely summarize more technical monographs on tobacco product regulation.

The current chapter provides an overview of what is meant by tobacco product regulation, examples of different regulatory approaches, and the rationale for adoption of these approaches. Subsequent chapters focus on guidance and recommendations (Chapter 2), needs and resource assessment (Chapter 3), steps necessary to develop and implement tobacco product regulation (Chapters 4 and 5), and specific issues, including the regulation of novel tobacco products (Chapter 6) and testing and disclosure of tobacco product contents, emissions and design features (Chapter 7).

## 1.1 WHAT IS TOBACCO PRODUCT REGULATION?

Tobacco product regulation refers to the regulation of any aspect of the contents, design or emissions of tobacco products (see sidebar), as well as any related regulatory or public disclosure of information.

Many tobacco control measures regulate where and how tobacco products may be sold, marketed, or used. These include licensing requirements for retailers, restrictions on sales displays or advertising, taxation of products, restrictions on smoking in public places, and adoption of health warnings or other packaging restrictions. The term tobacco product regulation is broad and for many jurisdictions it encompasses the presentation, labelling and packaging of the tobacco product. However, for the purposes of this handbook, the discussion on tobacco product regulation will be restricted to tobacco control interventions on the physical design and chemical content or emission of the products, and on identifying and regulating aspects of tobacco product design that play a role in maintaining or increasing product use

and harm. For purposes of this handbook, the concept of tobacco product regulation also encompasses regulation of tobacco and related products (TRPs). Some of these products, such as electronic nicotine delivery systems (ENDS), do not contain tobacco and most governments do not consider them tobacco products.

### **Definitions from the Partial Guidelines on Implementation of Articles 9 & 10 of the WHO FCTC.**

**Contents** means constituents with respect to processed tobacco, and ingredients with respect to tobacco products. Ingredients include tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients).

**Design feature** means a characteristic of the design of a tobacco product that has an immediate causal link with the testing and measuring of its contents and emissions. For example, ventilation holes around cigarette filters decrease machine-measured yields of nicotine by diluting mainstream smoke.

**Emissions** are substances that are released when the tobacco product is used as intended. In the case of cigarettes and other combustible products, emissions are the substances found in the smoke. In the case of smokeless tobacco products for oral use, emissions are the substances released during the process of chewing or sucking, and in the case of nasal use, the substances released by particles during the process of snuffing.

Product regulation can include restrictions on which products are legally permitted for sale. For instance, health authorities may choose to restrict the sale of products containing a specific chemical ingredient, such as menthol, or to regulate physical design features, as in the case of cigarettes with a reduced diameter, marketed as slim or super-slim. Health authorities may set upper limits on toxicant emissions, or require that products meet specific criteria, such as fire safety standards. Product regulations may also establish health or other evaluation criteria for new products to be introduced to a market. Requirements that establish measurable pass/fail criteria may be called performance standards, while those that specify design or manufacturing criteria are called technical standards. Alternately, product regulation can require that all tobacco products in the market are identified to health authorities, or that basic product information, such as nicotine content is measured and reported.

Different aspects of tobacco product regulation support each other but are also separable: it is possible to require disclosure of the contents, design features, and emissions of tobacco products without setting performance standards, and the reverse is true. However, in general, requests for product information disclosure should be made with the purpose of using gathered information to learn about and understand tobacco products and the market, with the purpose of informing future regulation.

It may be appropriate or desirable, based on a country's needs and resources, for health authorities to choose one or more delineated approaches while excluding others. This choice will differ depending on the national regulatory climate and available resources (see Chapter 3).

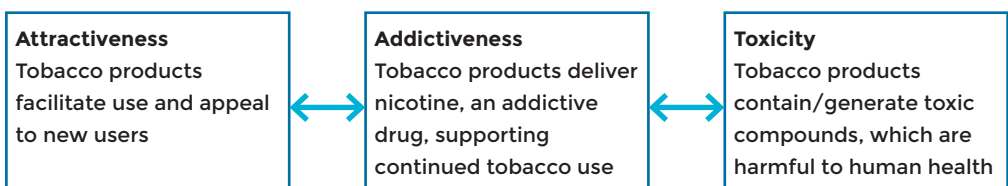
Decisions and reports of the WHO FCTC Conference of the Parties have addressed many aspects of tobacco product regulation, such as:

- FCTC/COP7(14) Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC;
- FCTC/COP7(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems;
- FCTC/COP6(12) Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC;
- FCTC/COP6(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems;
- FCTC/COP5(13) Electronic nicotine delivery systems, including electronic cigarettes: Report by the Convention Secretariat; and
- FCTC/COP5(9) Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control: Report of the working group.

## 1.2 WHAT PRODUCT FACTORS ARE DETERMINANTS OF TOBACCO USE AND HARM?

The devastating public health impact of tobacco products is due to a combination of three main factors: attractiveness, which results from product characteristics that encourage the use of tobacco products by a large proportion of the global population; addictiveness, which results mainly from the active drug nicotine contained in tobacco products, that makes users unable to limit consumption or quit tobacco use; and toxicity, which results from users exposure to toxic compounds that are contained in or generated by tobacco products, even when used as intended (6). Fig. 1 provides an illustration of the interplay between these three factors.

**Fig. 1. Factors supporting the negative health consequences of tobacco products**



There are many different forms of tobacco products. Manufactured cigarettes, the predominant form of tobacco used worldwide, account for more than 90% of global tobacco sales (7). Other forms of tobacco products include *bidis*, *kreteks*, cigars, smokeless tobacco, roll your own tobacco, pipe tobacco, waterpipe tobacco, heated tobacco products (HTPs) and other novel tobacco products. Forms of tobacco products can differ significantly with respect to their attractiveness, addictiveness and toxicity. These differences may lead to greater or lesser risk profiles among these products, which could have implications for human health.

For example, tobacco products with fewer toxicants may lead to lower rates of disease and death among individual users, as established by clinical and other research; products that do not deliver nicotine effectively or which are harsh or difficult to use may have a more limited population impact due to reduced use. Nonetheless, all forms of tobacco products are toxic, all encourage and support use and addiction, and all have the potential to cause harm. Reduced exposure to toxicants may or may not translate to better health outcomes.

## Attractiveness

The content and emissions of a given tobacco product are determined by design choices of the manufacturer, beginning with the tobacco(s) type and processing methods. Additives are non-tobacco substances used in processing, as well as to support other aspects of product design, such as flavouring or colouring. Other product components can include filters, paper, adhesives, inks, capsules and batteries, or power sources.

In general, all tobacco products are engineered to make them attractive. This is accomplished in part by making products that are easy and pleasurable to use (e.g. by the addition of flavours); by supporting perceptions of reduced risk (such as by the introduction of ventilation or use of white filter tipping to counter health concerns); by reinforcing aspirational characteristics related to product use (e.g. elegance or masculinity); and by minimizing or masking negative product characteristics.

Each of the physical aspects of tobacco product design play a role in how products are perceived and used, including the look, feel, smell, taste and other sensory characteristics of the product and emissions. Further, the tobacco industry is continuously seeking to make tobacco products more attractive by modifying existing product design features or introducing new ones. An example is the introduction of cigarettes with an ever-smaller circumference (slim, super-slim, ultra-slim) to connote femininity and reinforce perceptions of reduced smoke delivery and weight loss. Another innovation is the placement of capsules in cigarette filters that release flavours such as menthol when actively crushed. These and other product innovations are effective in:

- creating or increasing the “curiosity to try” factor;
- encouraging experimentation through product novelty, e.g., sizes, shapes, colours, flavours;

- making the product more palatable to experimenting new users through sensory attributes; and
- providing a variety of products that are attractive to different users and populations with unique characteristics, e.g. as defined by age, gender, ethnic or cultural background, socioeconomic status and health concerns.

## Addictiveness

Nicotine is a compound occurring naturally in tobacco; it is a central nervous system (CNS) stimulant and is the primary addictive component in tobacco products (8). On its own, nicotine is extremely harsh and irritating. Tobacco products are designed by manufacturers to support greater and/or more effective nicotine exposure, by reducing the natural physical or sensory barriers associated with nicotine, while also increasing the rate and speed by which nicotine is delivered and absorbed. Manufacturers accomplish this in a variety of ways:

- reducing or masking the harshness and irritation of nicotine and tobacco;
- increasing the nicotine content or delivery of the product;
- facilitating the bioavailability of nicotine (i.e. absorption into the bloodstream) through manipulation of product chemistry;
- introducing non-nicotine compounds that have their own CNS effects or which interact with or increase the effects of nicotine;
- providing a range of products and nicotine delivery levels allowing new or novice users access to lower nicotine/milder products, and graduating users to higher nicotine products; and
- ensuring flexibility of nicotine dosing (allowing users to adjust nicotine to optimum level).

## Toxicity

The toxicity of tobacco products reflects their underlying chemistry. More than 2500 chemical compounds are found naturally in tobacco, and there are over 7000 chemicals present in tobacco smoke (9, 10). Of these, more than 150 are toxic, including over 70 that are identified carcinogens (chemicals that cause cancer or lead to the development of cancer) (11, 12, 13). The hundreds of additives used in tobacco products can further contribute to toxicity or alter the chemistry of the tobacco product (14). In cigarettes and other combusted products, design characteristics such as size, length, paper, filter and ventilation affect the composition of generated smoke compounds. Power capacity is a significant factor in the emissions of HTPs and other novel TRPs.

Manufacturers have made publicized efforts to reduce the level of some toxicants generated by commercial tobacco products through changes in tobacco product content, design, or emissions. In most cases these efforts have failed to demonstrate reduced population harm. For example, so-called low-tar cigarettes were developed and marketed as having reduced toxicity, as reflected in lower levels of

machine-measured tar, nicotine, and carbon monoxide (TNCO) in smoke. The reduced smoke deliveries were produced in part through the addition of ventilation holes in the filters, which enabled smokers to inhale greater quantities of smoke from the cigarettes, offsetting the machine reductions in delivery. Further, these product design changes resulted in a perception of decreased product toxicity among smokers, making the products more appealing to those concerned about health risks.

Today, newer HTPs are being marketed as reduced risk products, with industry-funded studies claiming a significant reduction in the formation of harmful and potentially harmful constituents, relative to the standard reference cigarette used in laboratory-based measures (not in humans) for some products. These products are promoted as “pleasant and safer” alternatives to conventional cigarettes, with “cleaner” or “smokeless” emissions due to the claimed absence of combustion (burning), which is responsible for the generation of hundreds of toxic compounds associated with conventional cigarettes. Irrespective of manufacturer claims, considerable scientific evidence is necessary to support claims of reduced risk to individuals exposed to toxicants resulting from these products. Increased appeal of these or other so-called reduced risk products could also offset reductions in measured toxicants or emissions.

### 1.3 HOW CAN TOBACCO PRODUCT REGULATION IMPROVE PUBLIC HEALTH?

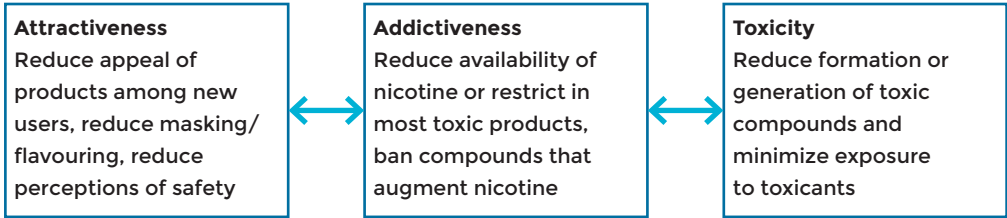
The above model of product use and harm indicates multiple routes by which tobacco product regulation can contribute to addressing the health impact of tobacco product use.

Policies could target:

- attractiveness by banning the use of candy or other flavours that appeal to youth, eliminating design features (e.g. ventilation) that support ease of use or reduced perceptions of risk (e.g. ban on use of spices and herbs such as cinnamon, ginger and mint used to improve the palatability of tobacco products);
- addictiveness by limiting nicotine content of tobacco, regulating aspects of product chemistry such as tobacco pH or factors relating to nicotine absorption, regulating the use of non-nicotine compounds that enhance the effects of nicotine or support nicotine dependence, and/or eliminating nicotine within the most toxic categories of tobacco products (e.g. combusted products); and
- toxicity by seeking to reduce or eliminate known tobacco toxicants (e.g. tobacco-specific nitrosamines generated during tobacco fermentation), placing limits on the use of toxic additives, reducing emissions, and/or barring the introduction of new products that pose unknown health risks.

None of the above policies should be understood to support manufacturer claims of reduced risk.

**Fig. 2.** Use of product regulation to address the health consequences of tobacco products



Effective regulation of tobacco product contents, design and emissions can significantly reduce tobacco demand and use, and the resulting burden of disease. If products are made less appealing and more difficult to use, fewer people will begin or continue using tobacco products. If tobacco products are made less addictive, or minimally addictive (as proposed in the United States, described below), the amount and frequency of use can be expected to decrease. If overall exposure to tobacco product toxicants is reliably lowered, population harm may be reduced even if large numbers continue to use these products.

Tobacco product regulation works in conjunction with other tobacco control policies. For example, setting and raising taxes, smoke-free environments, textual and pictorial health warnings on tobacco product packaging, and bans on advertising, promotion and sponsorship of tobacco products all serve to reduce tobacco use.

Tobacco product regulation can also be used to counter tobacco industry strategies that (knowingly or unknowingly) increase the attractiveness, addictiveness and/or toxicity of products. Disclosure can help a health authority to gain a better understanding of tobacco products on the market, which will facilitate appropriate action to effectively regulate those products (i.e. using the information submitted by manufacturers to inform future regulation). In doing so, health authorities should be careful that public disclosures or other regulatory interventions do not create the unintended impression of safer products. For example, prohibiting additives may create an impression that products carry reduced risks as a result.

There is a strong interplay in how aspects of product design affect tobacco product attractiveness, addictiveness and toxicity. For example, sugars increase the perceived mildness of tobacco products and support ease of use and appeal of tobacco products. At the same time, the combustion of sugars contributes to the formation of acetaldehyde in burnt products, which has been demonstrated to support addiction in animal studies (15). Pyrolysis and combustion of sugars can also generate acrolein, a known respiratory and cardiovascular toxicant (16). Thus, the regulation of sugars would have implications across multiple aspects of tobacco product use and harm.



## 1.4 WHAT ARE EXISTING AND EMERGING APPROACHES TO REGULATING TRP?

Relatively few countries currently regulate what is in tobacco products or how they are made, despite considerable progress in other areas of tobacco control. Many health authorities are hesitant to begin or expand work in tobacco product regulation. This is due in part to perceptions that product regulation is highly technical in nature, that it is only appropriate for countries with advanced tobacco control policies, that it requires substantial resources and capacity that lower-income countries cannot easily support, and that manufacturers can and will use their superior knowledge of products and tobacco science to circumvent regulations. Another factor limiting adoption of product regulation is inadequate understanding of how tobacco product regulation can support other tobacco control efforts, i.e. by shifting the paradigm of how tobacco products are viewed, identifying new and unanticipated health threats, and reducing demand.

Approaches to tobacco product regulation and the scientific basis for each approach are briefly outlined below. More detailed case studies of specific approaches to tobacco product regulation, as enacted globally, are presented in subsequent chapters.

### Testing and disclosure to health authorities

Testing and disclosure measures for the contents, emissions and/or design features of tobacco products enable health authorities to evaluate compliance, monitor products and product changes, and assess the intended and unintended consequences of regulation. Because of this, testing and disclosure provide a common basis for other product regulation including performance and technical standards. Since it is recommended that the burdens of tobacco product testing and disclosure fall primarily on manufacturers rather than health authorities, testing and disclosure is an appropriate initial step in tobacco product regulation even in the case of low-income or low-resource countries (LIC) (see Chapter 3). Strategies to ensure compliance and to maintain and analyse collected data must also be considered. A more detailed discussion of the role and implementation of product testing and disclosure is provided in Chapter 7.

### Product standards for toxicants or emissions

Many countries have established regulations to limit machine-measured cigarette smoke emissions, primarily for TNCO. For example, the Tobacco Products Directive (TPD2) (17), which governs the regulation of tobacco products in the European Union (EU) (see Chapter 5), is consistent with its preceding legislation (TPD1) (18), which specifies maximum TNCO levels for cigarettes in order to limit the scope of products allowable in the market. The scientific consensus, however, is that policies regulating machine-measured smoke emissions have not lowered the risks for diseases caused by smoking (19, 20). Further, labelling measures requiring the dis-

play of TNCO yields may have done more harm than good, by leading smokers into believing that switching to lower-emission products is an alternative to cessation.

The WHO Study Group on Tobacco Product Regulation (WHO TobReg) has proposed the use of performance standards to mandate a reduction in toxicant yields by identifying the mean emissions or other achievable measure and disallowing brands with higher levels from the market (20). Using this approach to establish limits for selected, modifiable toxicants in cigarette smoke emissions may be a first step for progressively lowering overall toxicant emissions. However, no countries have yet implemented such an approach.

## Regulation of flavours/flavoured products

Flavoured products are found in all regions of the world and across most forms of tobacco product. Flavours can include recognizable food compounds such as vanilla or cocoa, chemical compounds with taste or odour sensations, and sweeteners such as sugars. Flavoured products are used more frequently by younger populations and encourage experimentation and facilitate use among novice users. Product flavours can serve to mask the harshness of tobacco and/or nicotine, and can increase the reinforcing or addictive action of nicotine by providing a pleasurable sensory cue that becomes associated with the drug effect. Several countries have adopted regulations restricting or banning non-tobacco flavours in tobacco products (see Chapter 4).

## Regulation of nicotine

In July 2017, the United States Food and Drug Administration (US FDA) announced nicotine reduction as part of a comprehensive multi-year roadmap toward addressing the negative health consequences of tobacco use (21). A proposed rule for setting limits on nicotine in cigarettes was made public in March 2018 (22). Nicotine reduction could support public health objectives by eliminating the primary incentive (nicotine) to use the most harmful (combusted) tobacco products while maintaining availability of nicotine in less harmful forms for those who remain addicted. Many significant hurdles remain before this approach can be realized, such as better understanding of the health effects of ENDS and novel TRPs, and consideration of how to regulate health claims and communication of risk in the context of nicotine reduction. Moreover, many questions regarding the feasibility and practical implementation of this approach remain (21). However, there is clear evidence that reducing the nicotine content of cigarettes to a very low level can reduce dependence in smokers (23, 24). This approach is consistent with the recommendations of WHO TobReg (25). While it is likely that a nicotine reduction approach could be applied to other tobacco products, this would require further study and documentation and will need to be carried out within the context of a comprehensive tobacco control programme.

## Regulation of other product features

Flavour capsules have been demonstrated to support experimentation and use among young or novice smokers. Regulations to limit or ban the use of flavour capsules in tobacco products has been successfully pursued by jurisdictions including Germany and Belgium; and a ban of flavourings in tobacco product components such as filters, papers, packages, capsules, or any technical features allowing modification of the smell, taste or smoke intensity of the product, is now in place in the entire EU (see Chapter 5). Other product features that could be targeted include cigarette or TRP dimensions (slim, super-slim), filter and paper colour or appearance, and cigarette ventilation.

## Reduced ignition propensity standards for cigarettes

Lit cigarettes that are laid down and left unattended smoulder and can ignite upholstery, furniture, bedding, textiles, or other materials. This has been observed most often in cases of smoking in bed or smoking while under the influence of alcohol, illicit drugs or medication. Every year a considerable number of people around the world are injured or die (e.g. from burns or smoke gas poisoning) as a result of fires caused by cigarettes. In order to reduce the risk of starting fires and to prevent a significant number of resulting injuries and deaths, cigarettes can be designed in such a way that the cigarette self-extinguishes when not puffed or when left unattended. These cigarettes are known as reduced ignition propensity cigarettes (RIP) cigarettes.

COP6 (14) and Section 3.3.2.1 (iii) of the Partial Guidelines for implementation of Articles 9 and 10 of the WHO FCTC both recommend that Parties should require that cigarettes comply with an RIP standard, taking into account their national circumstances and priorities, and that in so doing Parties should consider setting a performance standard that corresponds at a minimum to the current international practice, regarding the percentage of cigarettes that may not burn their full length when tested. Parties should prohibit any claims by the industry suggesting that RIP cigarettes would be unable to ignite fires. Development of these recommendations took into account an extensive survey of regulations relating to RIP cigarettes, in high-income, middle-income, and low-income countries.

## Educating the public

Disclosure of product information to the public can be an important facet of tobacco control policy. Disclosure can take different forms including health and picture warnings on packages and published data on product contents or emissions. Given the potential for product-specific information to mislead tobacco users about relative risks, care must be taken with respect to communicating useful information to the public about the contents and emissions of tobacco products. Indeed, some jurisdictions have established regulations intended to eliminate misleading labeling on cigarette packs such as numerical ratings of TNCO (see “Product standards for toxicants or emissions”, above). Regulation of packaging can act in conjunction

with product regulation to further reduce misconceptions about harm. For example, standardized plain packaging is helpful in reducing misperceptions about the risks of tobacco products and the appeal of these products to young people. While not the focus of the present handbook, guidelines for Articles 11 and 13 of the WHO FCTC define packaging and labelling requirements, including standardized packaging.

## Regulating novel tobacco and related products (TRPs)

As evidence-based policy interventions are put in place to control the marketing and sale of conventional tobacco products, the tobacco industry has expanded to other markets, and at the same time introduced products like HTPs, which are promoted by companies as preferable or safer alternatives.

The WHO FCTC defines tobacco products as all products that are manufactured for consumption and are made either entirely or partly from tobacco leaf. Because WHO FCTC obligations apply in respect of all tobacco products, WHO FCTC obligations apply also to new product categories including HTPs (1). Definitions of the phrase “tobacco products” under domestic law differ from one jurisdiction to another. In some countries, the definition of tobacco products extends to all tobacco-derived materials, including nicotine, or to include products that are consumed in a similar manner and with similar presentation and mode of use to tobacco products. A more detailed discussion is provided in Chapter 6.

For ENDS, generalizable conclusions cannot yet be drawn about the ability to assist with quitting smoking (cessation), their potential to attract new youth tobacco users, or interaction in dual use with other conventional tobacco products and TRPs. Future independent studies should address these effects, as well as the safety and relative risks of TRPs. and relevant COP decisions including FCTC/COP7(9), which invited Parties to consider applying regulatory measures to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS and/or electronic non-nicotine delivery systems (ENNDS), as appropriate to their national laws and public health objectives. These recommendations are particular to ENDS, and are not applicable to HTPs. Some jurisdictions may define ENDS as tobacco products; those which do not should follow WHO’s recommendation from COP7/(9) in their regulation. Until such evidence becomes available, health authorities have an important role to play to effectively regulate these products to prevent access to minors and non-smokers. Again, further in-depth discussion is provided in Chapter 6.

## Tobacco product bans

Several jurisdictions, including the EU, have adopted laws limiting the sale of certain forms of smokeless tobacco. Other countries have banned flavoured cigarettes. Bhutan is the only country that has banned the sale of all forms of tobacco products, although this ban has not fully prevented tobacco products from being readily available. Many countries have banned the introduction of ENDS pending evidence

to support their reduced risk. Data to evaluate the impact of product bans on population health and other impacts, such as on government revenue, remain limited.

## **Premarket review and authorization**

Most countries regulate the introduction of new drugs and how they may be marketed and sold. The United States may be unique in that tobacco product manufacturers must apply for and receive an order from the US FDA before new tobacco products can be marketed. The 2009 Family Smoking Prevention and Tobacco Control Act provides three pathways to market a tobacco product, with the Pre-Market Tobacco Product (PMTA) pathway as the primary route for all new tobacco products. Under this pathway, a manufacturer must demonstrate that the new tobacco product is beneficial to the United States population as a whole, including users and non-users. This powerful tool allows FDA to authorize or deny the marketing of a new tobacco product based on the determination of whether it is appropriate for the protection of public health. Countries could consider premarket authorization as a way to restrict or control the introduction of new forms of products for which the health risks remain unknown.

## Chapter 2.

# INTERNATIONAL GUIDANCE ON TOBACCO PRODUCT REGULATION

The Partial Guidelines on the implementation of Articles 9 and 10 of the WHO FCTC (4) set out policy recommendations regarding the attractiveness of tobacco products, as well as the disclosure of information on the contents of tobacco products. Guidance regarding the addictiveness and toxicity of tobacco products may be provided at a later stage. All Parties to the Convention are strongly encouraged to align their regulatory activities with the recommendations of the Partial Guidelines, and countries not yet Party to the Convention are encouraged to become Parties or to follow the Partial Guideline recommendations as international standards. Technical support to countries is made available by WHO to aid the implementation of the Partial Guidelines at the country level.

These include WHO expert advisory and regulatory groups, such as the WHO Tobacco Laboratory Network (WHO TobLabNet), which develops methods for testing tobacco products, the WHO TobReg, which puts forward evidence-based policy recommendations on tobacco product regulation, and the Global Tobacco Regulators Forum (GTRF), which serves as a platform for regulators to share experience and facilitate information exchange. In particular, WHO TobReg publications (including both the Technical Report Series and Advisory Notes) will be useful in addressing particular topics.

Information on best practice and the effectiveness of interventions constitute additional resources for countries considering tobacco product regulation. A review of regulatory experience, further developed as case studies throughout the remainder of this handbook, is provided to assist health authorities to identify good practice, potential challenges to implementation and/or unanticipated outcomes.

## 2.1 WHAT IS WHO'S GUIDANCE ON REGULATING TOBACCO PRODUCTS?

Article 9 of the WHO FCTC addresses the regulation of tobacco product contents and emissions; Article 10 addresses the regulation of disclosure of information on tobacco product contents and emissions (see sidebar). The Partial Guidelines were adopted by COP4 in 2010, to assist Parties in meeting their treaty obligations (4).

### **Article 9 - Regulation of the contents of tobacco products**

The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

### **Article 10 - Regulation of tobacco product disclosures**

Each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to health authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.

At COP7, the COP added new language to the Partial Guidelines on the disclosure and regulation of product characteristics, as well as language on the disclosure of information on the contents of tobacco products that reference analytical laboratory methods developed under the auspices of WHO (26, 27).

It is important to note that, contrary to claims by the tobacco industry, these guidelines are in effect. The regulatory measures advocated by the Partial Guidelines are to be treated as minimum standards and do not prevent Parties from adopting more extensive measures. Article 2 (1) emphasizes this same point.

The Partial Guidelines recommend the following for the regulation of tobacco product ingredients. Parties should:

- prohibit or restrict ingredients that may be used to increase palatability in tobacco products;
- prohibit or restrict ingredients that have colouring properties;
- prohibit ingredients in tobacco products that may create the impression that they have a health benefit; and
- prohibit ingredients associated with energy and vitality (e.g. stimulants).

In order to regulate the ignition propensity of cigarettes, the Partial Guidelines encourage Parties to:

- set a performance standard that at a minimum corresponds to the current international practice regarding the percentage of cigarettes that may not burn their full length when tested according to the RIP method;
- require tobacco manufacturers to test ignition strength, report the results to the responsible authority and pay for implementation of the measures;
- require that all cigarettes comply with a RIP standard, and establish the necessary enforcement mechanisms; and
- avoid any claims suggesting that RIP cigarettes would be unable to ignite fires.

The Partial Guidelines also specify recommendations on disclosure of tobacco product information to health authorities and the public. Health authorities need accurate market information to determine regulatory needs and priorities. COP recommends:

- the disclosure of tobacco manufacturers' and importers' general company information; and
- informing every person of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke in a meaningful way.

The Partial Guidelines emphasize the importance of a comprehensive system for monitoring, compliance and enforcement to ensure effective tobacco-product regulation. The costs of financing such a system should be placed on the tobacco industry and retailers, through options such as designated tobacco taxes, tobacco product registration fees, and annual tobacco surveillance fees (see Chapter 7).

On the regulation of product characteristics, COP7 included a new recommendation to Parties to regulate all tobacco product design features that increase the attractiveness of tobacco products, in order to decrease the attractiveness of these products and reduce appeal (27).

On the disclosure of product contents, COP7 also made additional recommendations (27) to:

- consider requiring manufacturers and importers of tobacco products to disclose to health authorities at specified intervals, information about the contents of their tobacco products by product type, and for each brand within a brand family;
- consider specifying that standards agreed by the Parties to the Convention or recommendations by WHO TobLabNet be used by the laboratories performing testing on behalf of the manufacturers and importers of tobacco products when requiring the testing and measuring of contents as Parties deem appropriate;
- consider specifying that WHO TobLabNet Official Method SOP 04 on the determination of nicotine in cigarette tobacco filler (28), be used by country laboratories performing the test on nicotine on behalf of the manufacturers and importers of tobacco products;
- consider requiring that every manufacturer and importer provides to health authorities a copy of the laboratory report that shows the product tested and the results of the testing and measuring conducted on that product; and
- consider asking for proof of accreditation or membership in WHO TobLabNet or be approved by competent authorities of the Parties in question of the laboratory that performed the testing and measuring.



## 2.2 DOES INTERNATIONAL TRADE LAW PLACE LIMITS ON TOBACCO PRODUCT REGULATION?

World Trade Organization (WTO) rules limit the ways in which WTO Members may restrict or regulate trade in goods and services, including through the use of tariffs (customs duties) and non-tariff barriers to trade, such as regulatory measures. WTO rules also oblige WTO Members to ensure minimum standards for the protection of intellectual property rights.

WTO rules stem from more than 20 agreements. These include the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (TBT Agreement), the General Agreement on Trade in Services and the Agreement on Trade-Related Aspects of Intellectual Property Rights. WTO rules are enforced through a system of dispute settlement between its Members. Only WTO Members (governments) may bring a complaint alleging that another Member has violated a WTO-covered agreement.

Tobacco product regulation has been the subject of a dispute under WTO law in *US–Clove Cigarettes* (29, 30). In this dispute, Indonesia brought a claim relating to a United States law prohibiting the sale of cigarettes with a characterizing flavour, other than menthol or tobacco. Indonesia argued that the ban violated the TBT Agreement on the basis that the ban discriminated against clove cigarettes from Indonesia and was more trade restrictive than necessary to protect human health.

Although there are several WTO covered agreements applicable to tobacco product regulation, as *US–Clove Cigarettes* shows, the TBT Agreement is the most relevant. Accordingly, this section summarizes the TBT Agreement by reference to *US–Clove Cigarettes*. In the event that a measure is considered to violate WTO law, the offending Member is ordered to bring its law into conformity with WTO law within a reasonable period of time.

### The TBT Agreement

The TBT Agreement applies to technical regulations and standards. Technical regulations are mandatory requirements that set out product characteristics. Technical regulations can require that a product take a particular form or prohibit a product from taking a particular form. In the tobacco control context, technical regulations include measures such as packaging and labelling measures and tobacco product regulations. Among other things, the TBT Agreement establishes obligations with respect to necessity, non-discrimination and transparency.

#### **Necessity**

Article 2.2 of the TBT Agreement obliges Members to ensure that technical regulations are not more trade restrictive than necessary to achieve a legitimate objective, such as protection of human health. This obligation is supplemented by Article 2.4, which obliges Members to use relevant international standards as the basis for tech-

nical regulations, except when such international standards or relevant parts would be ineffective or inappropriate for the fulfilment of the legitimate objectives pursued. Article 2.5 presumes that health measures in accordance with international standards do not create unnecessary obstacles to international trade under Article 2.2.

In determining whether a measure is more trade restrictive than necessary, a WTO panel weighs the contribution a measure makes toward achievement of its goal against the trade restrictiveness of the measure, in light of the consequences of non-fulfilment of the objective. The regulation adopted must be the least trade restrictive means of achieving the government's objective, of those means that are reasonably available. The regulation must also not be applied in a manner that results in arbitrary or unjustifiable discrimination, or as a disguised restriction on trade.

In *US–Clove Cigarettes*, a WTO panel considered whether the United States restriction on clove flavoured cigarettes was more trade restrictive than necessary to protect human health under Article 2.2. Despite the regulation being highly trade restrictive (a complete product ban), the Panel rejected Indonesia's argument and this aspect of the Panel's decision was not appealed. In reaching its decision, the panel referred to the Partial Guidelines adopted by the COP, though without considering whether those guidelines constitute international standards for the purposes of Article 2.5 of the TBT.

### **Non-Discrimination**

Article 2.1 of the TBT Agreement prohibits both discrimination on the face of a measure (*de jure*) and discrimination in effect (*de facto*). In *US–Clove Cigarettes* Indonesia argued that the United States regulation discriminated (in effect) against Indonesian products because it prohibited clove cigarettes (primarily imported from Indonesia) but not menthol cigarettes (primarily manufactured in the United States). The USA argued that it had prohibited clove but not menthol cigarettes because clove cigarettes are particularly attractive to youth.

The Panel rejected the USA argument and found that the regulation discriminated against cigarettes produced in Indonesia in favour of cigarettes produced in the United States. The Appellate Body upheld this decision. In doing so, the Appellate Body found that clove and menthol cigarettes are sufficiently competitive in the United States market to be considered like products (30). The Appellate Body also found that the prohibition of clove but not menthol resulted in less favourable treatment of imported products because the regulation fell most heavily on imported products and was not based solely on a legitimate regulatory distinction between the two product classes. In the latter respect, the Appellate Body emphasized that clove and menthol each mask the harshness of tobacco and that clove and menthol cigarettes are each attractive to youth (30).

### **Transparency: notification and public obligations**

The TBT Agreement also imposes notification and publication obligations on Members. Article 2.9 of the TBT Agreement obliges WTO Members to notify other Members of an impending technical regulation if that regulation is not in accordance with a relevant international standard, or where no relevant international standard exists.

These obligations apply if a technical regulation may have a significant effect on trade of other Members. Paragraphs 1–4 of Article 2.9 require a Member to, among other things, publish a notice, notify other WTO Members, provide particulars of the proposed regulation upon request, allow a reasonable time for comments, and take those comments into account. As a general rule, six months is considered a reasonable period of time for the purposes of Article 2.9.

The TBT Agreement also establishes the TBT Committee, which provides a forum within which WTO Members can discuss measures before they are implemented, with a view to avoiding formal dispute settlement. A number of tobacco control regulations have generated debate within the TBT Committee, including Canadian and Brazilian measures to reduce the palatability and attractiveness of tobacco products, and Australian regulations requiring the plain packaging of tobacco products.

## Conclusion

*US–Clove Cigarettes* provides a good case study in which core principles of WTO law were applied to a tobacco product regulation. The Panel upheld the necessity of the product ban, but found that the effect of exempting menthol cigarettes was discriminatory. Since *US–Clove Cigarettes* other WTO Members have introduced similar bans on flavoured cigarettes without controversy at the WTO. For example, the 2014 EU TPD2 (17) obliges EU Member States to prohibit cigarettes with characterizing flavours, including menthol. In this instance, the risk of discrimination was one of the rationales for covering all flavours. Further discussion of the EU court case can be found in Section 5.2. The 2012 Brazilian directive banning the great majority of tobacco additives (described in Case Study 6) was similarly contested by the tobacco industry before the Brazilian Supreme Court on the basis of its unconstitutionality rather than through the WTO.

## 2.3 WHAT ARE DIFFERENT COUNTRY EXPERIENCES IN REGULATING TOBACCO PRODUCTS?

Tobacco product regulation is evolving and will continue to evolve alongside the development of new tobacco and related products and markets, and the science on tobacco product use and harm.

As new regulations are considered, the experiences of different countries and health authorities can provide critical insight into potential obstacles or unanticipated consequences to proposed regulations, as well as identify approaches that have proven more effective. In the WTO example above, the exclusion of menthol-flavoured cigarettes in a flavour ban raised legal challenges with respect to clove-flavoured cigarettes that might otherwise have been avoided.

A series of case studies are highlighted in subsequent chapters of the handbook. These case studies provide the opportunity to identify some of the successes and pitfalls of prior regulatory efforts while reflecting the important differences in policy objectives and/or political or social context.

- **Chapter 3** presents India as a country with existing tobacco product legislation but insufficient regulatory capacity or resources to implement legislation (Case Study 1); and Burkina Faso as a country that has successfully implemented tobacco product legislation in a low-income setting (Case Study 2).
- **Chapter 4** considers the experiences of Chile and Canada as instances in which revisions to initial product regulations were needed to support intended policy objectives. In Chile, revisions followed a legal challenge by the tobacco industry and included the development of a more relevant science base to support new regulations (Case Study 3); in the case of Canada, the revisions were necessitated by an unanticipated market response to the initial regulations, which were successfully identified by post-market surveillance (Case Study 4).
- **Chapter 5** uses EU TPD2 to provide an extended illustration of the processes necessary to support implementation of regulations. Chapter 5 also highlights the challenges of harmonizing regulations across multiple jurisdictions in the EU (Case Study 5); the process toward overcoming legal challenges to a flavour ban implementation in Brazil (Case Study 6); and unintended consequences of printing emission values on packages under TPD1 (Case Study 7).
- **Chapter 6** highlights two examples of regulation of novel or new TRPs: first, restrictions on the introduction of new and modified products in the USA (Case Study 8); and second, a ban on menthol-flavour capsules in Germany (implemented under TPD1) (Case Study 9).

Tobacco product regulation must be evidence-based, suited to the needs of the country in question, and regularly monitored and reviewed for effectiveness, taking account of new evidence and knowledge to meet regulatory targets. Challenges facing health authorities in regulating tobacco products include: legal, technical and political opposition by the tobacco industry, the diversity and technical complexity of tobacco products including novel TRPs, and the lack of a regional science base and/or developed capacity for surveillance, testing and enforcement of product regulatory measures.

Countries planning to regulate tobacco products should not minimize or overlook necessary preparatory work, given the tobacco industry's demonstrated ability to find and exploit loopholes with legal and other challenges. It is important that countries and agencies coordinate evaluation and regulatory action to prevent the industry from exploiting regulatory differences to its advantage. The tobacco industry's history of deceiving health authorities and misrepresenting scientific data to support its interests shows that the industry and affiliated organizations cannot and should not be relied upon to regulate themselves. Any regulatory system should be independent of industry, and health authorities should seek the advice and support of other public health experts to address questions of reliability or interpretation of data.

## Chapter 3.

# FIRST STEPS: ASSESSING REGULATORY NEEDS AND CAPACITY

If appropriately pursued and implemented, tobacco product regulation can contribute significantly to global efforts to reduce the mortality and morbidity caused by tobacco use. However, there are many potential barriers: the apparent complexity and technical nature of product regulation; the diversity of tobacco products available in various markets; insufficient data on the effectiveness and potential health and economic benefits of specific policies; tobacco industry interference; and inadequate tools/techniques and/or limited resources to actively pursue product regulation. As a result, health authorities tend to shy away from utilizing this powerful tool to complement other tobacco control interventions. A clear understanding of the objectives, processes involved, desired outcomes and overall gains for regulating tobacco products is crucial in formulating effective regulatory mechanisms at the country level.

This chapter presents the first steps the health authority should take in determining what regulatory policies are available, and how they relate to policy objectives and the setting of priorities. To begin with, an assessment of regulatory needs and resources is required. Next steps include exploring possible approaches to regulating tobacco products, anticipating possible outcomes, consulting with stakeholders and deciding on a preferred regulatory approach. The following questions can serve as a starting point for health authorities to analyse their situation, identify regulatory gaps and tailor regulatory responses.

- Where are you now? Assessing resources and capacity.
- What do you need? Identifying priorities for regulation.
- What is possible? Gathering and evaluating evidence.
- What should you do? Making the decision to regulate.

### 3.1 WHERE ARE YOU NOW?

#### ASSESSING RESOURCES AND CAPACITY

Health authorities should first take stock of what regulatory mechanisms may already be available, beginning by engaging with relevant stakeholders, including internal stakeholders within the health sector and concerned departments, and external stakeholders within other non-health sector agencies. Wide engagement

is crucial at this stage to establish whether there are existing laws in place (i.e. a general safety products directive, medicines agency, etc.), which may already cover the products in question.

Questions that could help a health authority in establishing a baseline profile.

- What is the national tobacco product regulatory authority?
- Is there a tobacco control law(s)? What does this cover?
- Which products are legally defined as tobacco products? Are there other laws in place that cover tobacco products?
- Are there other governmental departments involved in tobacco-product regulation (trading standards, medicines agency, consumer products, customs, etc)?
- Do existing laws regulate the contents and emissions of tobacco products?
- Does the country have funds for tobacco product regulation?
- Has the country developed tobacco product regulation guidelines under the law?
- Is there any existing mechanism for monitoring the regulation of tobacco products? Who is involved and how does the country engage with those involved?
- Which tobacco products are manufactured in the country and which are imported? Has the tobacco industry adopted regulatory or other criteria from an importing country for the tobacco products which are being exported?
- If the country does not manufacture tobacco products and only imports products, does the law provide for regulation of imported tobacco products? Does it cover cross-border sales?
- Is there scope to amend an existing law to incorporate new tobacco regulation priorities?
- Does the country have facilities for testing the contents and emissions of tobacco products, whether within the government or outside (private/industry)?
- Does tobacco product regulation form part of regular tobacco surveillance?

Health authorities should review their existing tobacco control laws and policies and compare with the recommendations set out in the Partial Guidelines on Articles 9 and 10 of the WHO FCTC (see Chapter 2) to establish where efforts are needed to tighten or extend tobacco product regulation. The Partial Guidelines are publicly available (4) and countries are encouraged to consider recommended measures to regulate tobacco products in their jurisdictions based on specific needs. Note that although the guidelines provide a useful framework for the regulation of tobacco products, countries are further encouraged to adopt measures beyond these recommendations as and where possible (31).

## 3.2 WHAT DO YOU NEED?

### IDENTIFYING PRIORITIES FOR REGULATION

Countries must consider the available evidence base regarding product use in their own markets, as well as the range and diversity of available products. Key information that could help a country in establishing tobacco regulatory priorities includes:

- established traditions of tobacco product use, such as social use of waterpipes or a cottage industry of smokeless products with minimal controls;
- recent introduction of new or novel products;
- information on tobacco use prevalence among specific groups;
- direct targeting by the tobacco industry of particular products to specific groups;
- higher levels of harmful chemicals within a particular product compared to the same product in other countries; and
- knowledge of global products and priorities on tobacco product regulation.

Country data (i.e. morbidity and mortality, where available) as well as regulatory needs and capacity should guide the selection of regulatory priorities. This will allow emphasis to be placed on product regulation interventions that are relevant to the country and that are non-resource intensive, especially in low-resource settings. The following questions will help to identify priorities.

- What are your objectives for regulation? What are the key potential gains of introducing regulations or other interventions?
- How do you measure success? Is there a potential skills gap in conducting evaluations internally? Will external expertise be needed?
- What are the resources needed – human, infrastructure (e.g. laboratory, information technology) and monetary? Is there a need to budget for tobacco regulation activities or are there regular funds allocated to tobacco-product regulation?
- Do you need to reprioritize based on available resources or available data/evidence? Should you consider less resource-intensive options, for example by starting with the regulation of disclosures (see below)?
- What are the estimated resources required to establish the regulatory system?
- What tools or infrastructure are needed (e.g. relevant databases, translation, electronic reporting platform, auditing, access to standardized testing methods, etc.)?
- What are the necessary timelines to gather evidence, evaluate evidence, consider options, prepare legislation, obtain the necessary approvals, engage with internal and external stakeholders, analyse findings, introduce legislation, and communicate to the public?
- How will you sustain tobacco product regulation activities over time? What mechanism(s) will be used?

In cases where data on products and product use is not readily available, regulation may serve as a mechanism for obtaining necessary data. For example, a country could start with implementation of WHO FCTC Article 10, placing the onus on the industry to identify tobacco products and report information on the contents and emissions of products to health authorities (27). This will help countries to gather knowledge on the products available in their markets, which can inform future policies.

Health authorities should be aware that measures must still be put in place to guarantee the correctness or accuracy of data submitted by industry. One approach is to mandate the industry to submit an attestation that the information submitted is true, so that if data is found to be unreliable, incomplete or inaccurate, health



authorities can penalize the industry. This can include fines and may be as severe as imprisonment, depending on the country and the authority's regulatory powers. Health authorities with the capacity to verify industry reported data should periodically check the completeness and accuracy of such data. Further discussion of options to support testing in cases where a country's own capacity is limited is provided in Chapter 7.

The needs and priorities of a country are likely to shift over time due to changes in the tobacco market and the population, and the outcomes of prior regulation. Even after regulatory priorities are identified, further exercises must be conducted periodically to determine whether reprioritization is necessary, as well as to articulate objectives and targets, identify the tools and resources needed to realize set objectives, enumerate expected outcomes and identify key stakeholders (internal and external).

## CASE STUDY 1: INDIA

### CHALLENGES TO SUPPORTING EXISTING LEGISLATION DUE TO LIMITED CAPACITY

In India, the provisions governing tobacco product regulation are covered in the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA 2003) (32). The law provides for testing of tobacco products for their contents and emissions (tar and nicotine) and depicting the same on tobacco product packages. However, despite a comprehensive law, most of the provisions relating to testing of contents and emissions have yet to be fully implemented. This is mainly due to the lack of capacity, expertise and the technical knowledge to set up a fully functional tobacco testing laboratory that will allow testing and measurement of contents and emissions in all forms of tobacco products. The government is under pressure from various sectors including the legal cases filed against it to implement the provisions for testing, and commitments have been made by the government regarding timelines for setting up the tobacco testing laboratories in court of law and Parliament. Although the government identified existing labs in various sectors for building tobacco testing capacity, it faced initial reluctance from these laboratories to take on testing of tobacco products.

Nonetheless, India has taken positive steps to overcome identified challenges and has built a case, with the backing of decision-makers and pressure from tobacco control groups, leveraging available local and global resources and engaging with the right experts to support implementation of tobacco control policies. With extensive and sustained technical support from WHO and funding support by the Ministry of Health & Family Welfare, three laboratories are at an advanced stage to become fully functional to address the regulatory provisions under COTPA 2003. The persistence with which India has overcome initial challenges provides a blueprint for other countries in surmounting tobacco product regulation challenges in low-resource settings. The steps adopted by India are as follows:



- including regulatory provisions in the tobacco control law, making it WHO FCTC compliant;
- providing funds from regular Ministry of Health budget to establish and maintain laboratories;
- coordinating among relevant stakeholders;
- learning from best practice, as adapted for the individual country;
- getting policy-makers support to establish capacity;
- engaging with experts both locally and globally (including other Parties and WHO);
- identifying existing facilities which could be optimized to incorporate testing and measurement of tobacco products;
- engaging with relevant partners for training of technical laboratory staff;
- strategic positioning of laboratories to best serve the whole country and the diverse tobacco products in the region; and
- partnering and engaging with the relevant networks (e.g. becoming a member of WHO TobLabNet).

### 3.3 WHAT IS POSSIBLE?

#### GATHERING AND EVALUATING EVIDENCE

Gathering information is an important step in formulating regulation, as a robust evidence base is necessary for sound policy and to ensure a regulation succeeds in achieving its objectives. Emphasis should be placed on the best available evidence (33), which may include scientific evidence, expert opinion, empirical evidence, private communications, and/or country experience. The strength and relevance of evidence must be clearly evaluated. Several techniques are available for grading/determining the strength of evidence which to a large extent are assigned according to the source/type of evidence (34). For example, when considering scientific evidence, meta-analysis and systematic reviews are viewed as very strong evidence and of good quality, while expert and anecdotal evidence carry less weight.

Gathering evidence is not a process that needs to be undertaken in isolation. Consideration should be given to other parties with relevant information and/or interest in the proposed regulation. Questions to consider in identifying parties and evidence include the following.

- Who are the key internal stakeholders (government departments and experts, such as economists, legal experts, statisticians, tax experts, communication professionals, policy-makers, etc.)?
- Who are key external stakeholders or agencies (tobacco industry, members of the public, civil society organizations, media, etc.)?
- What other sources of information are available to build evidence (i.e. global data reports, WHO, WHO FCTC Partial Guidelines, scientific publications, private communications, WHO Advisory Groups (WHO TobLabNet, WHO TobReg, and GTRF), WHO FCTC Knowledge Hubs, tobacco industry websites and company reports, market reports and data, conferences, legislation of other countries)?

- Can regional or international cooperation foster experience-sharing and the use of an existing evidence base? How can this be facilitated?

An important consideration, especially when formulating policy, is the independence of research studies or other evidence from the tobacco industry, as this may be biased. Article 5.3 of the WHO FCTC obliges Parties to protect public health policies with respect to tobacco control from the commercial and other vested interests of the tobacco industry (35). In scrutinizing and examining the strength or relevance of evidence, a health authority should consider authorship of the research to determine whether the content is biased, based on the affiliations of the author(s), how the study is funded and any limitations that might render the evidence less relevant for the purpose intended or for the particular country in question.

Health authorities should engage effectively with identified key stakeholders when considering policy options and engage relevant expertise, as every option must be properly evaluated, balancing the risk against anticipated benefits. A stakeholder analysis to determine the importance and relevance of each stakeholder in combination with a public consultation is one useful approach, which will ensure maximum outreach and the gathering of as much evidence as possible on proposed interventions to facilitate a well-considered decision. This will aid a thorough evaluation of these interventions on several parameters, including businesses, populations, target groups and public health.

Analysis of the evidence is the most critical step and can be conducted in stages throughout the process or at the end of the evidence-gathering exercise. This step can extract meaningful information and trends to examine whether there is a strong evidence base to substantiate proposed interventions and to determine whether reprioritizing of regulatory needs or amendment of these interventions will be necessary. It can also support the identification of negative or unintended consequences and how these might be minimized.

The information, data and reports required to facilitate decision-making will be guided by the purpose and scope of the regulation and should be considered explicitly at the outset of the consideration process. It is important to determine the kind of analyses that will be needed. Both qualitative and quantitative methodologies can aid decision-making. Although many evaluation tools are publicly available online, it should be determined in advance what specific expertise is necessary to support analysis, such as data analysts, economists, information technology or other experts.

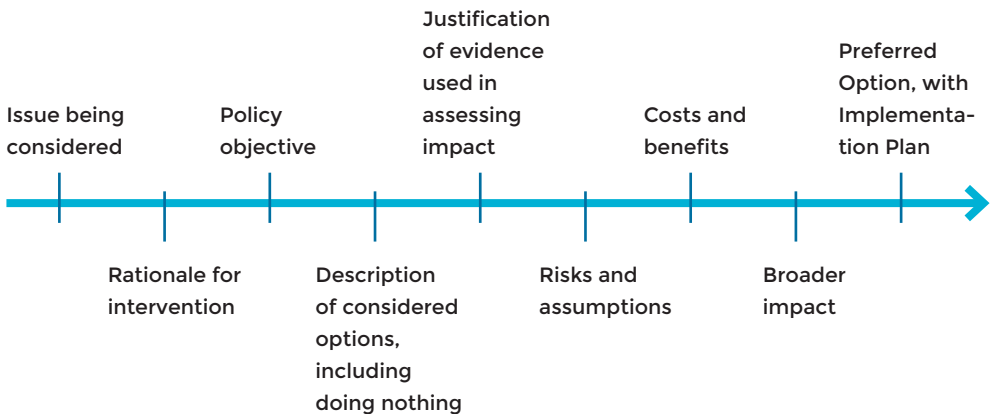
### **3.4 WHAT SHOULD YOU DO?**

#### **MAKING THE DECISION TO REGULATE**

Arriving at the best legislative opportunity(ies) requires the clearest and most reliable evidence. Health authorities should also consider the practicability of proposed interventions; timing for the process, corrections, engagement and approvals; the

feasibility of implementation; resources and sustainability; impact on public health, the economy (including small and big businesses) and the environment; and evaluation of unintended consequences. In reaching a decision, the health authority should explicitly set out the issue under consideration, the basis for the proposed regulatory intervention(s), the aim and intended outcomes/effects, and provide a description of all options explored (including doing nothing), setting out monetized and non-monetized costs, benefits, evidence/justification, and risks/assumptions for each option. Further, the broader impact of the proposed intervention should be articulated, and justification provided for the preferred option and how it will be implemented, managed, measured and enforced. An impact assessment is a useful way of organizing these steps and there are publicly available templates which can be employed for this purpose, an example of which is provided in Fig. 3. The components identified in this decision-making process are recommended and low-resource countries could follow the same approach in setting out regulatory options to decision-makers.

**Fig. 3. Steps in the decision-making process, from initial consideration of a regulatory intervention, to the decision to regulate (36)**



The success of a proposed policy hinges on the rigour of the process above (or a similar process) and the identification of the preferred option, duly substantiated with concrete evidence. Such a holistic approach to evidence-gathering/evaluation – and the presentation of the information gleaned from the process into comprehensible and concise policy language for decision-makers, which could be an expert group, steering group, independent or parliamentary committee – will aid the formulation of sound policies, with a better chance of achieving set objectives.

Additionally, provisions should be made to amend policies to suit changing regulatory needs and to incorporate new and emerging evidence, as necessary. A stepwise or tiered approach to implementation can also be explored in low-resource settings to make the best use of available resources and to maximize benefits.

Post-regulation surveillance should be considered since it provides a critical means to measure the effectiveness of interventions, to monitor, review and evaluate prog-

ress and to capture data to improve regulations should be considered. The following questions can guide post-regulation surveillance.

- Is the country able to meet the targets set for regulation?
- Who is the custodian of regulatory information?
- What is the mechanism available to assess the data generated through regulation?
- Are there any provisions for evaluation of regulatory practices in use?
- What are these provisions and what will be the frequency of evaluation?

## CASE STUDY 2: BURKINA FASO

### DEVELOPING CAPACITY FOR PRODUCT REGULATION AND TESTING IN A LOW-INCOME COUNTRY (LIC)

Burkina Faso became a Party to the WHO FCTC in October 2006 and has focused its efforts on aligning tobacco product regulations with the provisions of the WHO FCTC (Articles 9 and 10), despite challenges it has faced as a LIC in formulating and implementing tobacco control policies. The country passed a Tobacco Control Act in 2010 focusing on the packaging and warning labels of tobacco products (37), with implementing legislation adopted in 2011 and 2015 for effective implementation of the law. The WHO report on the global tobacco epidemic 2017 (38) identified Burkina Faso as one of three LICs that has adopted strong health warnings since 2014, and it was also listed in the same report as one of the countries with the greatest level of achievement in terms of health warning labels.

As Burkina Faso is not exempt from the difficulties faced by many LICs, including tobacco industry interference, lack of resources, lack of political will, and lack of relevant expertise, the lessons learned and approaches used to surmount these challenges and implement product regulation may be helpful to other countries facing similar situations.

#### **Joining relevant international tobacco regulation networks, such as WHO TobLabNet**

Burkina Faso became a member of the WHO Tobacco Laboratory Network in 2005, and by virtue of its active involvement and participation in the activities of the network, has strengthened its research and testing capacity, specifically in the area of tobacco-product regulation.

#### **Collaborating with WHO as a WHO Collaborating Centre (WHO CC) on Tobacco Product Testing and Research**

WHO advances its work programmes via several mechanisms, including collaborating centres, institutions designated by the WHO Director-General to carry out activities to support WHO's work programmes, under the Organization's leadership. Burkina Faso has been very active in international tobacco control, including the WHO FCTC, which led to the designation of the

national laboratory of public health – Laboratoire National de Santé Publique, Direction de la Toxicologie, du Contrôle de l’Environnement et de l’Hygiène, Ouagadougou – as a WHO CC in 2013. The laboratory participated in the development of internationally validated methods for the contents and emissions of tobacco products mandated by the COP to the WHO FCTC.

### **Laboratory for Tobacco Product Testing**

By developing its tobacco product laboratory testing capacity, Burkina Faso can now test products available on its market to meet obligations in line with the national law. It can also help to test the contents and emissions of tobacco products in its region and its methods are available for other countries. Additionally, it can access the most up-to-date information, varied expertise and diverse resources to inform national tobacco product regulation due to its active involvement in international tobacco control activities.

### **Generating Buy-In of Senior Government Officials**

Politics play a pivotal role in tobacco control in most countries and can determine the fate of a proposed intervention (39). Continued engagement and support from key government officials and ministers could be the catalyst needed to push regulations through. Sustained support in the form of resources and maintaining priority status on the political agenda can also make a significant difference. The positions of officials regarding tobacco control policies will dictate the progress made in tobacco control both in the short- and long-term, which means that their support is essential. The backing of comprehensive national tobacco control laws passed by the Council of Ministers and subsequent actions of key players in the government has added significant weight to how these regulations are perceived.

## Chapter 4.

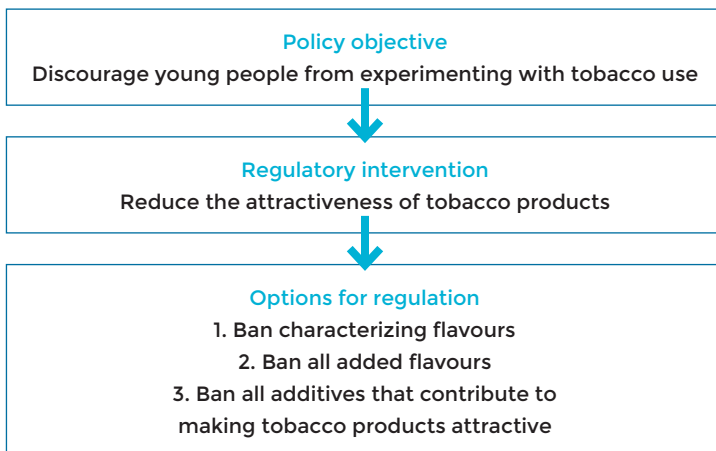
# REGULATORY CONSIDERATIONS IN ADVANCE OF IMPLEMENTATION

This chapter presents issues that may prove useful to health authorities in the process of selecting a measure for regulatory intervention. Specifically, consideration of these and similar issues may help authorities to select the most appropriate regulatory measure, to refine the measure to accurately reflect the problem at hand and the context in which it appears and, ultimately, to contribute to the measure's successful implementation.

For demonstration purposes, three regulatory options are the focus of the discussion, each with a different scope (narrow, intermediate and broad). All are intended as interventions to reduce the attractiveness of tobacco products under an overall policy objective of discouraging young people from experimenting with tobacco use (see Fig. 4). These different options are considered through four foundational regulatory issues, each framed as a question.

1. Have you gathered the relevant information?
2. What will you include in the regulatory text?
3. Is the measure you have chosen practical?
4. How will you know if the regulation has done its job?

**Fig. 4.** Example of three potential regulatory options to address the policy objective of discouraging tobacco use among young people



## 4.1 HAVE YOU GATHERED THE RELEVANT INFORMATION?

Information to support a decision to regulate the contents, design or emissions of tobacco products may be collected from population surveys on tobacco use prevalence and/or attitudes and beliefs, domestic tobacco market data, public opinion research, product testing, peer-reviewed studies, tobacco product information disclosures (industry submitted data), lessons learned from other countries (both problems and solutions), civil society, or even from tobacco industry sources (e.g. complaints from competitors). This information can help to determine that a tobacco-related problem exists, to define the specific nature of the problem, and to identify potential solutions.

In the example presented in Fig. 4 above, information collected could be used to help answer the following questions.

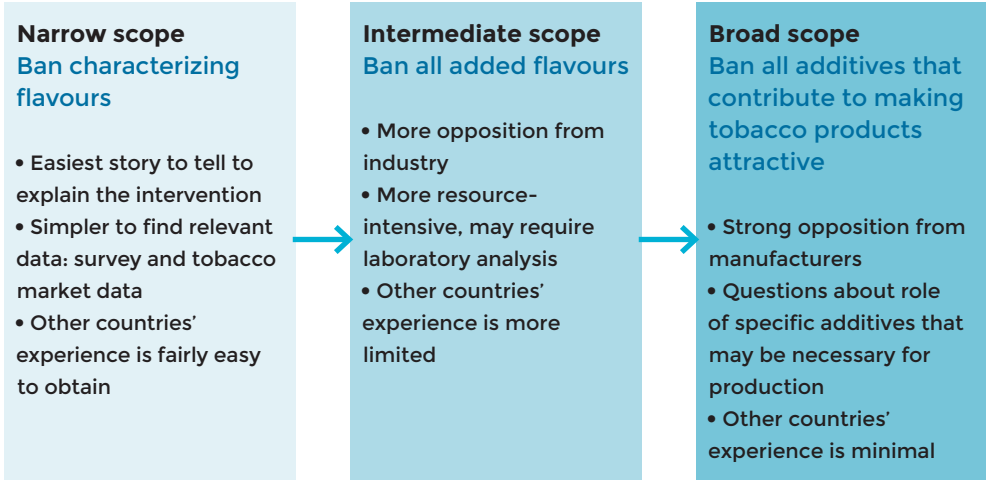
- Are there flavoured tobacco products available in the domestic market? If so, what product types are they and what flavours are available?
- Are there tobacco products promoted as containing additives other than flavours in this market (e.g. honey, other sweeteners, vitamins)?
- When were these products introduced into the market? What proportion of total tobacco sales do they represent?
- How are these products marketed?
- Do flavoured tobacco products make up a significant proportion of the products used by youth or young smokers, or other populations of concern?
- Has there been any increase in uptake of these products among young people?

Answers to these questions will help point to an intervention of appropriate scope (ranging from narrow to broad). The choice of regulatory option is impacted by the information gathered, including the quality and robustness of data, and how it is used, as shown in the following scoping chart (see Fig. 5). For example, in the case of a country in which one or more specific flavours (e.g. menthol or vanilla) have been demonstrated to play a sizeable role in the uptake of tobacco use among young people, a regulatory strategy might be focused on products that are characterized as “flavoured products” on the basis of marketing, packaging, and overt product characteristics (narrow scope). On the other hand, the primary issue of concern might be products that are made more palatable through the addition of flavour compounds, whether or not these flavours are communicated directly or explicitly to consumers. In this case, a complete ban on use of flavours might be considered (intermediate scope), or this ban might be further extended to include other additives that increase attractiveness, such as sweeteners, humectants, colours, stimulants, or pH modifiers (broad scope).

While a broader regulatory scope may have greater potential to address the initial policy objective, or may even extend beyond this objective and have a greater impact in reducing the use of tobacco, it may also require a greater and/or more robust evidence base to support it, and more work may be needed to determine how it will be implemented, or to anticipate the potential consequences of such an action.

Alternatively, a step-wise approach may be an appropriate choice – instead of implementing a broad scope measure all at once, incremental regulatory steps could be introduced over time. The choice of scope is discussed further below.

**Fig. 5. Options for scoping a regulatory intervention – narrow, intermediate and broad**



In the case of narrow-scope regulatory intervention (to ban tobacco products marketed or otherwise categorized according to flavours) domestic tobacco market data and the existing literature showing how flavoured products make tobacco products more attractive to young people may be adequate to support the intervention, depending on the national context. The intermediate-scope option may require further evidence; for example, it might be supported by product-specific data gathered on tobacco ingredients from manufacturers using a disclosure mechanism, or from independent laboratory analyses, showing that flavour additives are found in tobacco products even in the absence of marketing or other overt characterization of these products as flavoured.

Further determination could focus on whether specific flavour additives contribute to making tobacco products more appealing (i.e. via sensory testing or surveillance). The link between flavour compounds and experimentation or use among young people may be more difficult to demonstrate than in the case of products openly characterized by their flavours. While the amount of work required to gather relevant information may increase as the scope of the option widens, the potential positive impact on public health also increases. For example, the intermediate option prevents manufacturers from continuing to sell the same flavoured products while removing only labelling or other identifiers (e.g. selling removing the identifier “menthol” but continuing to add menthol to the product). The broad scope option puts further limits on industry innovation and its ability to attract new users by preventing other additives such as sugars or colours from substituting for the elimination of flavour compounds.



Most health authorities must address the critical issue of whether they have sufficient legal powers to advance the regulatory options under consideration. If an authority does not have all the necessary powers for some options, it may need to narrow the scope of the preferred options, or change the law to provide required powers.

## CASE STUDY 3: CHILE

### BAN ON MENTHOL PRODUCTS IS STRUCK DOWN

Chilean law grants the Ministry of Health authority to restrict or ban substances added to tobacco when the substances are shown to increase levels of addiction, and health risks. The Ministry of Health sought to ban menthol tobacco products under this authority in 2013, but the Office of the Comptroller General (a separate government body) ruled that the Ministry had failed to demonstrate that menthol directly increases addiction, harm or risk.

According to the data provided by the National Health Survey (ENS 2016–17) in a national representative sample of people aged 15 years and older, the consumption of menthol cigarettes corresponds to 35.5% of current smokers (45.4% of women and 27.8% of men). On the other hand, the consumption of “click” cigarettes reaches 44.3% of current smokers (52% of women and 38.4% of men).

A proposal to amend the tobacco control law is currently under consideration, which seeks to ban the use of flavouring and additives such as menthol given that it is a component that promotes the initiation of tobacco use; and, directly or indirectly, increases addictiveness, harm, and risk for users. The bill was approved by a majority in the Health Commissions of both legislative chambers, and is due to be considered by the National Congress to become a national law. The bill requires a favourable vote in the two legislative chambers, as well as the President’s signature. The new government has stated its interest in supporting this bill.

## 4.2 WHAT WILL YOU INCLUDE IN THE REGULATORY TEXT?

Once the regulatory measure and scope have been decided, and the health authority’s legal powers have been confirmed as sufficient for that option, the regulatory text (whether it is legislation, decree, resolution or a similar legal document) must be drafted. This should be worded to address the immediate problem, but flexible enough to adapt to market response(s), such as industry innovation or new scientific evidence. Reviewing legislation from other countries and enquiring about their experiences may prove to be of enormous help in crafting robust regulatory text.

Care should be taken to draft the regulations such that they are clearly understood by the regulated entities. Likewise, the regulations should include clear and comprehensive definitions where needed. Consideration should also be given to unintended consequences and loopholes that could be exploited. In the example discussed in this chapter, an objective definition of what constitutes a characterising flavour<sup>1</sup> is needed to ensure the term is clearly and consistently understood. Aside from regulating the content of a tobacco product, countries should consider prohibiting “any representation of a flavour on the packaging” as a (visual) promotional element, as is the case in the EU.

Health authorities should be aware of unclear wording about exclusions, such as “ingredients which are necessary for manufacture” that may be used by the tobacco industry to challenge the intended scope of the intervention. Rather, aim for wording that is easy for a court to understand and apply.

Given the litigious nature of the tobacco industry, authorities may wish to prepare in advance for possible litigation. Given the national context, the industry may be likely to use constitutional arguments to oppose the proposed regulatory measure. To address this, provisions should be worded to protect the measure from such arguments. It may also be useful to ask subject matter experts or academic institutions to help identify expert witnesses ahead of time, in case this is necessary, and to advise on any additional information needs. Further, if a public consultation is conducted prior to the introduction of legislation, analysing the responses of the consultation to collate information that can assist with possible tobacco industry challenges, could prove very valuable.

In countries that are members of the WTO (or a regional trade group), the tobacco industry may try to use the country’s trade obligations to oppose a regulatory measure, a tactic that has become standard industry practice designed to slow down advancement in tobacco control (see Chapter 2). Again, it may be useful to plan ahead by wording provisions to limit the industry’s ability to undermine an intervention through trade obligations.

Other factors to consider in drafting a regulatory measure include:

- determining if enforcement powers are sufficient to seize products that do not meet the requirements, and/or to launch prosecutions;
- clearly identifying all the powers the enforcement agency will need;
- setting out penalties (e.g. fines, imprisonment) that will act as a deterrent – note that penalties for violating the law must be sufficiently severe to prevent manufacturers from treating them simply as the “cost of doing business”;
- establishing clear deadlines – for example, the timing of the coming into force of its provisions;
- writing the text in to facilitate the reporting of alleged violations by the general public, including non-governmental organizations;

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1 One example of a definition: In the European Union’s Tobacco Products Directive (2014/40/EU), “characterising flavour” means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product.

- ensuring clear designation of responsibilities, especially if there are more than two regulatory authorities involved in enforcement; and
- establishing clear timelines and procedures for making representations, especially in disputes.

Finally, it could be useful to consider holding not just manufacturers, but also tobacco importers, wholesalers, distributors and retailers, responsible for ensuring the products for which they are responsible meet regulatory provisions.

### **Seeking input and advice from other government authorities**

Depending on the national context, it may be beneficial to consult other government ministries on the proposed regulatory text to seek help or advice. Consider the following examples of sources and the nature of potential help.

- For a country that is a member of the World Trade Organization, consulting the trade ministry can help ensure that the measure is fair, non-discriminatory and meets the rules of trade between Member States.
- The customs ministry or authority can help address contraband arguments that could be raised by the tobacco industry.
- The agriculture ministry can provide help with mitigation measures, if local tobacco growers may be impacted by the proposed measure.
- The revenue ministry or authority can help with mitigation measures, if taxes on tobacco products may be impacted by the regulatory measure.
- The justice ministry can provide help addressing legal issues, including court challenges from the tobacco industry.

## **4.3 IS THE MEASURE YOU HAVE CHOSEN PRACTICAL?**

Another critical issue to consider is the practicality of implementing the preferred measure. It is useful to know and address, for example, answers to the following questions.

- Has a government agency been identified to conduct the compliance and enforcement activities related to the regulatory measure?
- If yes, does that agency have adequate resources? Does it have experience with tobacco products?
- Is it possible to adapt another existing regulatory framework on consumer products (i.e. cosmetics, etc.) to apply to tobacco products?
- Has the agency determined the approach to be used to monitor compliance? Have alternative measures been considered?
- If inspectors are to be designated to monitor compliance, will training materials have to be developed, will training be provided to these inspectors and how will this training be delivered?
- Does the health authority have access to facilities for compliance monitoring? Depending on the scope of the intervention, there may be a need for laboratory testing to verify compliance.

- If it does not have its own laboratory facilities, can the responsible authority access an independent (contracted) laboratory to conduct the appropriate testing?

It may be useful to build into plans the intention to revisit the selected approach after it has been in place (implemented) for some time to assess whether it continues to be effective.

In addition to the above considerations, it is also worth determining whether the scope of the regulatory measure (narrow, intermediate or broad, as set out in the example at the beginning of this chapter) has an impact on how easily it can be implemented. In many jurisdictions, for example, the compliance and enforcement activities for a narrow scope option would be the simplest to carry out (although determining what constitutes a characterizing flavour may prove challenging). A measure with an intermediate or broad scope will trigger the need for additional resources as they may involve laboratory testing and related development of appropriate analytical methods for the detection of flavours in tobacco products. On the other hand, relying on laboratory results may be a practical and straightforward way to obtain compliance.

#### **4.4 HOW WILL YOU KNOW IF THE REGULATION HAS DONE ITS JOB?**

Health authorities may benefit from determining – before implementing a regulatory measure – how to monitor the impact of the regulatory intervention on the initial problem. One way to do this is to use the information that helped to identify that there was a tobacco-related problem in the first place, selecting one or more indicators to allow progress to be tracked. Just before the intervention is implemented, it is useful to ensure that there is sufficient information to establish a baseline (against which future data can be compared), and that a plan is in place to continue collecting relevant information. Here again, subject matter experts may have useful advice on whether additional information should be gathered and how (e.g. such as through a survey).

It is also beneficial to consider whether the desired outcome(s) is measurable. Measurable indicators can help ensure that successes are captured and reported appropriately. It can be critical to ensure that compliance levels are effectively monitored, and to help assess whether the impacts measured (including successes) are tied to a low or a high level of compliance by regulated entities.

Monitoring public perceptions of the regulatory intervention may also provide useful information about the impact of the measure, and what (if any) additional action needs to be taken on this front. For example, has the measure led to misperceptions among the public, such as a belief that tobacco products have been rendered less harmful?

A solid understanding of the expected economic impacts of a regulatory intervention may also be useful to health authorities to support effective monitoring of the measure's impact. Such an economic cost analysis may strengthen an intervention by helping ensure the authority is well prepared to counter anticipated arguments from the tobacco industry. Key elements/information that may be useful in an economic cost analysis include:

- number and size of manufacturers and importers (small, medium and large) to be impacted by the measure;
- percentage and value of tobacco products manufactured in the country that will be impacted;
- capital costs expected, if any, for the purchase by manufacturers of new machinery and equipment;
- costs to the manufacturer, if any, for redesign of tobacco products, reporting of regulatory data or provision of samples for analyses;
- anticipated changes in product pricing, if any; and
- anticipated reductions in sales, measured both in terms of reduced quantity of tobacco products sold and reduced sales revenue.

Reviewing the above elements again some time (i.e. a two or five year point) after the measures have been implemented may help health authorities assess market response. Authorities may also wish to monitor other aspects of the market, in order to answer the following questions.

- Has prohibiting one feature of tobacco products – for example, characterizing flavours – led to the use of alternatives by the industry to circumvent the intent of the intervention?
- Has the industry found, and exploited, loopholes in the regulatory text?

Given the amount of work required to prepare for, implement and monitor results of a regulatory intervention, health authorities will ideally share results with other countries to help advance tobacco control globally. Coordination across countries can be especially important to anticipate problems or challenges and to prevent the industry from leveraging regulatory differences. Further discussion regarding coordination and sharing of data is provided in Chapter 2.

## CASE STUDY 4: CANADA

### IMPLEMENTATION OF A BAN ON FLAVOURS CIRCUMVENTED BY THE TOBACCO INDUSTRY

In the early 2000s, it was observed that flavoured little cigars began appearing on the Canadian market. Flavoured little cigars are similar to cigarettes, with appealing fruit and candy flavours. Sales data collected through mandatory industry information disclosure showed that these products were becoming increasingly popular. Sales of flavoured little cigars had experienced a threefold increase over a five-year period while the market for unflavoured cigars remained basically flat. By the second half of the 2000s, Canadian survey data indicated a significant use of little cigars

among youth. These data supported the notion that youth interest in these products could, in large part, explain the increased sales.

To address this problem, Canada introduced the Cracking Down on Tobacco Marketing Aimed at Youth Act (2009). This legislation prohibited the manufacture and sale of little cigars, cigarettes and blunt wraps that contained certain additives that contributed to making the products attractive, including most flavour additives (but not menthol). The legislation also prohibited any representation on the packaging suggesting the presence of a banned additive (40).

The initial legislation was soon circumvented by tobacco manufacturers. Through post-implementation monitoring of the marketplace, it was observed that the industry had made flavoured little cigars larger, and in doing so was legally able to continue offering flavoured products. A first response from government saw the ban on flavours extended to most types of cigars; it was followed by an amendment in 2015 in which menthol was prohibited. The extension of the initial flavour ban to menthol was based on information from surveys showing much higher levels of interest in tobacco products with menthol among youth and young smokers (40).

Studies following implementation of the menthol ban found that products previously sold as menthol continued to be presented at least temporarily with green colouring and descriptors emphasizing a “smooth taste”, suggesting that packaging may be used as a strategy to maintain attractiveness and undermine the public health benefits of the menthol ban (41). Other countries pursuing a ban on flavours may need to consider the use of marketing tactics as a means of circumventing policy goals.

## Chapter 5.

# IMPLEMENTATION AND POTENTIAL CHALLENGES

Following determination of the needs and resources available within a specific regulatory environment (Chapter 3), and careful consideration of policy approaches to achieve desired regulatory objectives (Chapter 4), the next step for the regulatory authority is implementation of policy. Steps necessary to achieve successful implementation will differ taking into account the unique political and legal environment of each country, the source and scope of regulatory authority, the nature of the regulatory objective, the strength of the science base and justification for the action, the degree of opposition to the measure, the availability of similar regulatory experiences to draw from, and other related factors.

This chapter will illustrate the potentially complex process of implementation through a discussion of the EU's 2001 Tobacco Products Directive (TPD1) (18) and 2014 (TPD2) (17) Tobacco Products Directive. The primary focus of the discussion below is on the rationale behind the approach adopted by the EU for TPD2, the need for reassessment and revision of prior actions, challenges to implementation, and the ways in which challenges were successfully addressed.

### 5.1 WHAT DOES IMPLEMENTATION OF TOBACCO PRODUCT REGULATION LOOK LIKE?

Tobacco use is responsible for an estimated 7 million avoidable deaths globally, including 700 000 in the EU, every year. Around 50% of smokers die prematurely (on average 14 years earlier). The vast majority of smokers start smoking when they are very young – according to the latest survey data, 52% of current or former smokers developed a regular smoking habit before their 18th birthday and 93% before the age of 26 (42).

To address this situation, the EU, together with its Member States, adopted various tobacco control measures in the form of legislation, recommendations and information campaigns. These policy measures include, for example, the regulation of TRPs on the EU market, restrictions on cross-border advertising and sponsorship, the creation of smoke-free environments, levying taxes and activities against illicit trade.

## The 2001 TPD (2001/37/EC)

Encompassing legislation on Tobacco Products was first adopted in the EU in 2001 with the Tobacco Products Directive 2001/37/EC (TPD1) (18). Earlier related legislation largely focused on individual provisions, such as setting tar limits (Directive 90/239/EEC) (43), product labelling (Directive 89/622/EEC (44), Directive 92/41/EEC (45)), and prohibition of oral tobacco (Directive 92/41/EEC) (45).

TPD1 already foresaw measures in relation to certain provisions, such as health warnings, cigarette TNCO limits, ingredient reporting, oral tobacco, emission reporting and product descriptions. Following its entry into force in 2001, the Commission reported twice on its application, in 2005 (46) and 2007 (47). These reports highlighted some of the TPD1's shortcomings, such as the need for better alignment with the WHO FCTC (for instance in terms of large mandatory pictorial health warnings and abolishing the printing of TNCO yields on cigarette packs), the need for a mandatory electronic reporting system, the challenges associated with the introduction of novel tobacco and related products, as well as efforts by the tobacco industry to circumvent existing law.

The review of TPD1 was explicitly anticipated in the law itself, and its revision to adequately reflect market, scientific and international developments had been repeatedly called for by the parliament and council of the EU. This revision became necessary for several reasons. New scientific evidence had emerged, for example on tobacco flavourings and the effectiveness of health warnings. Furthermore, new products, such as electronic cigarettes or ENDS and new flavoured tobacco products were introduced on the EU market. There had been developments at the international level, triggered for example by the WHO FCTC to which EU Member States had responded with different regulatory approaches. Thus, an important goal of the revision was to harmonize implementation of these international obligations and to ensure a consistent approach to non-binding WHO FCTC commitments, if there was a risk of diverging national transposition.

In the consideration of adapting policy measures, it was relevant to update those areas which were already harmonized under EU law to overcome obstacles for Member States to update national legislation in response to the changing market, as well as scientific and international developments. Furthermore, it was necessary to address product-related measures that were not yet covered by the TPD1, to avoid the possibility of heterogeneous developments in the Member States resulting in a fragmentation of the internal market. Finally, it was important to address the problem of circumvention of the existing law.

In addition to the negative impact of tobacco consumption on people's health, one of the most compelling reasons to strengthen the rules on tobacco products was the fact that smoking prevalence rates, particularly among young people, were still high compared to other jurisdictions with strong tobacco control policies. According to survey data at the time of the revision, prevalence rates in the EU were 28% among the overall population (aged 15 and above) and 29% among the younger age group of 15–24 years of age (48).



In summary, the new Tobacco Products Directive 2014/40/EU (TPD2) (17) seeks to improve the functioning of the EU's internal market for tobacco products, while assuring a high level of public health. A primary objective was to make tobacco products and tobacco consumption less attractive in the EU, in particular, to young people.

### **Outline of regulations specified in Tobacco Products Directive 2014/40/EU (TPD2)**

#### **Labelling and Packaging**

- Large mandatory pictorial health warnings
- General health warning/replacement of TNCO labelling by an information message
- No more promotional or misleading packages and elements

#### **Ingredient Reporting and Regulation**

- Ban on cigarettes and roll-your-own products with characterizing flavours
- Ban on additives or products with certain properties (e.g. containing additives that increase toxicity, addictiveness, or attractiveness)
- Ban on flavourings in certain components of tobacco products (filters, paper, packages, capsules)
- Mandatory electronic reporting of ingredients, emissions, and sales data
- Priority additives identified which are subject to enhanced reporting obligations

#### **Electronic Cigarettes**

- Safety and quality requirements
- Packaging and labelling rules
- Notification and monitoring

#### **Novel Tobacco**

- Prior notification and enhanced reporting

#### **Ban of oral tobacco maintained**

#### **Provisions on Cross-border Distance Sales and Herbal Products**

#### **Measures to Combat Illicit Trade**

## **Procedure of the revision**

In the course of the revision of TPD1, extensive consultations of citizens, stakeholders, NGOs and Member States were undertaken. Several studies were conducted to assess different policy options and scenarios. Finally, an extensive impact assessment (49, 50) was performed to present the qualitative and quantitative economic, health, social and environmental impact of the different options in order to identify the preferred option. The impact assessment (49) was published by the European Commission, together with its proposal for a revision of the law in December 2012. Fol-

lowing the negotiation process with the co-legislators, i.e. the European Parliament and the Council of the European Union, the revised TPD2 was adopted in April 2014.

TPD2 became applicable in EU Member States on 20 May 2016. Member States were required to bring into force the necessary laws, regulations and administrative measures to ensure full compliance and had to communicate to the Commission the text of those national provisions by this deadline. In line with the transitional provisions of the Directive (2014/40/EU), as of 20 May 2017, all products placed on the EU-market should comply with this law. The main components of TPD2 are outlined in the sidebar (Outline of Regulations Specified in the EU Tobacco Products Directive). A more comprehensive description of these provisions can be found in Annex 1, located at the end of this handbook.

## Implementation of TPD2

While the implementation of TPD2 is an obligation for EU Member States, the European Commission provides support to Member States by developing supporting mechanisms and tools or by supporting coordination and/or collaboration of relevant activities. In certain areas, the European Parliament and the Council have empowered the Commission to adopt additional legislative acts to implement TPD2. This secondary legislation outlines in further detail the rules governing the manufacture, presentation and sale of TRPs. Delegated and implementing acts have been adopted in the following areas:

- a new library of pictorial health warnings;
- the layout, design and shape of the combined health warnings for tobacco products for smoking;
- the position of the general warning and information message on roll-your-own tobacco;
- the reporting format for tobacco product ingredients, emissions and related data (including for novel tobacco products);
- a common notification format for electronic cigarettes;
- the technical standards for the refill mechanism of electronic cigarettes;
- a priority list of additives that warrant further examination;
- the rules and mechanism for determining whether tobacco products have a characterizing flavour, including the procedure and the establishment of a panel; and
- technical standards for the systems for tobacco traceability and security features.

Moreover, the Commission has written a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes.

In developing the implementing legislation, the Commission was supported by external contractors and scientific experts. In turn, the implementing legislation provided the basis for the establishment of the mechanisms supporting Member States in the practical implementation of TPD2, such as the EU Common Entry Gate (EU CEG) for reporting of information on tobacco products and electronic cigarettes,

and the Independent Advisory Panel on characterizing flavours in tobacco products. The Commission also established a Joint Action, financed under the EU Health Programme, allowing Member States to join forces in the TPD implementation.

TPD2 also provided mechanisms to adapt certain provisions in the future taking account of new developments, such as internationally agreed standards, scientific evidence, market developments or national measures. Examples include health warnings, emission standards or permitted levels of tobacco product additives. The Commission may also remove exemptions granted to certain product categories if there is a substantial change in circumstances (in terms of sales volumes or prevalence levels among young people).

## Reporting and monitoring

While the monitoring of national markets falls within the competence of Member States, the Commission facilitates discussions and exchange of information, experience and best practice between Member States, e.g. via the Joint Action and its Expert Group on Tobacco Policy. The Commission also monitors international, scientific and market developments.

By May 2021 the Commission shall report on the application of TPD2 and shall indicate elements of TPD2 which should be reviewed or adapted in the light of scientific and technical developments. Aspects of particular interest include plain packaging, novel tobacco products, changes in use patterns, tobacco ingredient regulation and reporting, slim cigarettes, electronic cigarettes and waterpipes.

## CASE STUDY 5: EUROPEAN UNION LEGISLATION ON TOBACCO PRODUCT FLAVOURS FOR 28 COUNTRIES

The EU faces a unique challenge when developing, negotiating, implementing and enforcing legislation for 28 Member States. TPD2 is the result of negotiations between the European Commission (who developed the legal proposal) and the co-legislators (European Parliament and Council).

In prior decades, EU Member States have sometimes adjusted the common product regulation by adopting, where appropriate, their own individual approaches: In terms of tobacco products legislation related to additives, some countries listed permitted additives (positive lists), some listed prohibited additives (negative lists) while others used a combination of both, or did not regulate the use of additives at all. Therefore, a harmonized approach on ingredients was necessary to improve the functioning of the internal market in the EU. During the preparatory phase of the TPD2, three options (in addition to the status quo) were assessed ranging from the prohibition of additives with specific properties to prohibiting all additives not

essential for manufacturing (an option similar to the Canadian and the Brazilian approaches). Details can be found in the impact assessment (49) presented by the European Commission and summarized in an executive summary (50).

In relation to flavours, TPD2 introduced a ban on tobacco products with characterizing flavours that will initially only apply to cigarettes and roll-your-own (RYO) tobacco (for a definition see Section 4.2). The implementation of this provision will be supported by an independent advisory panel of experts and a technical group of sensory and chemical assessors. Moreover, TPD2 foresees that tobacco products shall not contain flavourings in any of their components such as filters, papers, packages and capsules. Technical features allowing modification of the smell or taste of the tobacco products concerned, or their smoke intensity, are prohibited. These provisions are complemented by measures addressing the presentation of products: Among others, promotional or misleading features or elements on tobacco packages are prohibited as well as references to lifestyle benefits, taste, smell or flavourings – and this provision applies to all tobacco products on the market.

A general challenge during the revision of the TPD was to counteract the strong lobbying by the tobacco industry. For this particular policy area, some concessions were made, such as the initial exemption of some tobacco products (e.g. cigars, cigarillos, pipe and waterpipe tobacco as well as smokeless products) from the ban on characterizing flavours, and the postponement of the ban until 20 May 2020 for tobacco products with a characterizing flavour whose sales volumes in the EU represent 3% or more in a product category (51) (as is the case for mentholated cigarettes).

## 5.2 WHAT ARE THE CHALLENGES YOU MAY FACE?

The experience of the Commission and Member States illustrate legal, as well as practical challenges to implementation of TPD2, which are outlined below.

### Legal challenges

The EU continues to defend the provisions of the new TPD2 in the European Court of Justice. It successfully defended TPD2 in three cases, where the Court confirmed that TPD2 is valid and that the “extensive standardization of packaging, future EU-wide prohibition on menthol cigarettes and special rules for electronic cigarettes are lawful”. Several other court cases in relation to individual provisions, such as the ban on oral tobacco, the classification of chewing versus oral tobacco, the provisions on product presentation (promotional elements), use of pictorial health warnings and the additional transitional period for certain products with characterizing flavours are currently ongoing. The United Kingdom’s introduction of plain packaging was also challenged by the tobacco industry in 2016. In its landmark judgment on this case, the High Court ruled that the government’s regulations on plain packaging were lawful and that all grounds of challenge made by the tobacco industry had failed.

In two of the closed court cases (C-547/14, C-358/14) the plaintiff argued that the provisions on characterizing flavours would constitute a discrimination of mentholated versus other cigarettes. However, with a reference to an earlier WTO-case (see overview of this case in Section 2.2), the EU successfully argued that an exemption of menthol from the ban would constitute an unjustified difference of treatment and thus a discrimination of other flavours (52). Experience from these cases, as well as from ongoing related cases and from discussions with the Member States, indicate that the tobacco industry is making a concerted effort to keep menthol products on the market for as long as possible.

## Circumvention of regulations

Manufacturer efforts to circumvent TPD2 have been observed. Examples reported by individual Member States include the addition of flavour threads to packages to bypass the ban on products with a characterizing flavour; and the sales of paraphernalia, such as capsules, flavoured papers or package covers to circumvent the ban on products with flavour capsules, the ban on products with a characterizing flavour and the use of mandatory health warnings, respectively.

## Novel tobacco products

The industry has engaged in significant efforts to market novel TRPs, such as HTPs, which can pose challenges for the competent authorities, in particular regarding their classification. As far as the regulation of these products is concerned, it is an advantage that all tobacco products are covered by TPD2 and that manufacturers/importers are required to submit a prior notification (six months), accompanied by extensive information on all such products in order to place them on the market. Moreover, Member States can decide to introduce an authorization system for these products.

## Resources and infrastructure

Implementation of TPD2 is resource intensive, considering the tasks foreseen and the related mechanisms it entails – both for regulators at the EU and national level. For instance, competent authorities need to process and analyse a large amount of product-related data received from the industry via the EU CEG. The competent authorities of the Member States are obliged to publish the data while considering the need to protect trade secrets. Other examples include the assessment of test products by the independent advisory panel and the technical group of sensory and chemical assessors, as well as the provisions on the traceability system for tobacco products. LIC or low-resource countries may wish to consider the degree to which regulations obligate them to direct limited capacity and focus primarily on regulations for which compliance is more straightforward (i.e. without need for ongoing sensory or chemical assessment).

## CASE STUDY 6: BRAZIL

### INDUSTRY OPPOSITION DELAYED IMPLEMENTATION OF A BAN ON FLAVOURS BUT WAS ULTIMATELY UNSUCCESSFUL

On 15 March 2012, the Brazilian Health Regulatory Agency (ANVISA) issued a resolution banning the import or sale of tobacco products containing most additives including flavours (53). This was the first time that any country had banned all flavours in tobacco products, including menthol. However, this ban was not initially implemented pending the resolution of a legal challenge filed by Brazilian tobacco lobbying group Sinditabaco against ANVISA. In late 2012, the court ruled in favour of Sinditabaco, and suspended articles 6 and 7 of the ANVISA Resolution (54, 55). De facto, the tobacco industry had obtained a temporary judicial suspension of the ban on additives and flavours which it claimed threatened its business. ANVISA appealed this decision, with the hearing of the case scheduled on many occasions but always postponed. The case was finally heard before the Federal Superior Tribunal of Brazil in the autumn of 2017. In a landmark victory for tobacco control and public health, Brazil's Supreme Court of Justice rejected the constitutional challenge from the tobacco industry and ruled in favour of the ANVISA resolution (56). As of 1 February 2018, the ban on flavours and additives in tobacco products now holds across Brazil.

The two main arguments brought by the different stakeholders over the years were that this ban was unconstitutional, and that ANVISA had not produced scientific evidence demonstrating that the ban on flavours would serve public health purposes. Discrediting proven science is one of the many forms of tobacco industry interference (57). The industry sparks controversy to distract and confuse the public and governments, sowing the seeds of doubt on the scientific evidence. This is again confirmed by a recent study which confirmed that the information used by the tobacco industry to build some arguments against the bans proposed by ANVISA, was “generated through misrepresentations of legitimate sources and representations of illegitimate ones. ... It is likely that decision-makers do not have the time and perhaps the desire to scrutinize the strength of the information supporting the messages they receive from different interests. It will be important for tobacco control researchers to continue to explore the policy-making process in order to better understand what types of information enter this process and to what effect.” (58)

This case, in addition to showing that product regulation is of great concern for the tobacco industry, should serve as a good example for countries wanting to ban flavours in tobacco products. One of the lessons learned is that all countries should conduct ahead of time, during the preparatory phase of the regulation, a systematic work to commission and gather relevant research and scientific evidence, in order to leave no room for the tobacco industry to claim the lack of an established science base to support proposed regulations.

## 5.3 WHAT ARE POTENTIAL OUTCOMES FOLLOWING IMPLEMENTATION?

Implementation of TPD2 has triggered additional tobacco control measures in some EU Member States. Following the adoption of the TPD2, several Member States have introduced plain packaging (with the legislation already being applied in the United Kingdom, France and Ireland). This makes the EU the second jurisdiction to introduce plain packaging measures, following Australia's lead.

In the context of TPD2, some Member States have taken action to ban certain product categories, such as chewing and nasal tobacco. These actions have been pursued at the country rather than EU level in light of the specific situation in these Member States and justified by the need to protect public health. Sweden maintains the exemption to the ban on oral tobacco products that was granted when Sweden joined the EU in 1995. Moreover, TPD2 provides Member States on certain aspects with the possibility to introduce specific measures, for example to introduce an authorization scheme for novel tobacco products or to adapt rules on flavours for electronic cigarettes.

The adoption of stricter and encompassing rules through TPD2 should help to deter young people from experimenting with, and becoming addicted to, tobacco. As estimated in the impact assessment, TPD2 is expected to lead to a 2% drop in consumption of tobacco over a period of five years. This is roughly equivalent to 2.4 million fewer smokers in the EU. Governments and society should benefit from improved public health, namely longer healthy lives. The reduction in tobacco consumption resulting from the new measures is calculated to translate into annual healthcare saving of €506 million (US\$ 577 million). However, as non-compliant products were only recently fully removed from the EU market, it is currently too early for an empirical analysis regarding how the regulatory approach is working in practice. A comprehensive assessment will be carried out in the context of the reporting obligations that were assumed as part of TPD2.

## 5.4 HOW DO YOU RESPOND TO UNANTICIPATED OUTCOMES?

As indicated above, comprehensive changes to TPD1 were first identified as necessary by regulators following regulatory developments, the emergence of new scientific evidence and given the rapidly changing market of available TRPs. Provisions built into TPD1 supported review of the policy's effectiveness and outcomes, which made the need for these revisions clear.

Lessons from the EU experience highlight the importance of monitoring, not only of tobacco products and product changes, but also of outcomes spurred by regulatory interventions. Monitoring of outcomes can take the form of surveillance of beliefs



and attitudes as well as epidemiological or other health-based measures. The EU experience also emphasizes the importance of adaptability in a successful regulatory approach, as it may become necessary in the future to respond to unanticipated changes in the market, to new scientific or technical developments or to address circumventions of regulation, whether initiated by industry or users. Also necessary is the willingness of the regulatory authority to consider alternate approaches in these circumstances. A more in-depth discussion of implementation of monitoring and surveillance can be found in Section 4.4.

Tobacco product regulation cannot be considered or conducted in isolation given that the tobacco market is global. Regulatory action in one country may provide a useful starting point for other countries, especially those considering a similar approach or faced with a similar regulatory issue, as they are determining priorities or considering aspects of implementation, such as defining terminology, options, engagement, information or identifying potential loopholes or exceptions. Some regulatory action may influence the behaviour of industry in other jurisdictions, such as in setting priorities for product development, or where and how tobacco products are produced or exported for sale. Wherever possible, competent authorities should draw on the experiences of other countries that have considered and/or successfully implemented regulations in order to anticipate outcomes and challenges, sharing their own experiences in turn.

## CASE STUDY 7: EUROPEAN UNION INFORMATION ON TNCO-LEVELS

Regulatory experience can be informative in identifying outcomes that differ dramatically from the objectives which supported implementation. TPD1, adopted in June 2001 (2001/37/EC), included provisions requiring tobacco product manufacturers to print TNCO yields on cigarette packages.

The inclusion of TNCO yields (numerical descriptors) on cigarette packs at the time was intended to inform the public, especially consumers of cigarettes, about the machine measured amounts of analytes in the tobacco product to enable them to make informed public health choices. In parallel, references to elements (e.g. light, mild) suggesting that a particular tobacco product was less harmful than others was prohibited. However, consumers interpreted the information as a relative risk tool (i.e. one product seen as being safer or better than the other) (59). For example, cigarettes with a tar yield of 1 mg/cig were misconstrued as being safer than products with 10 mg/cig. Further, science demonstrated that machine-based smoke yields were poor measures of human exposure and risk, due to factors such as filter ventilation and smoking behaviour. As a result of this experience and evidence, the presentation of TNCO-values on tobacco packages was discontinued under TPD2.



## Chapter 6.

# NOVEL, NEW AND MODIFIED TOBACCO OR RELATED PRODUCTS

The market of available tobacco products is constantly changing, with new products and brands introduced, as well as modifications to existing brands through manipulation of tobacco blends, additives, papers, and other design components. Many new or modified products fall within the continuum of traditional combusted (cigarette, cigar, *bidis*) or non-combusted (moist snuff, *snus*, *toombak*) tobaccos that have been used for decades and whose health risks are well documented. However, a variety of novel tobacco products have also emerged in recent years. Examples include HTPs that use sophisticated electronics to control the generation of emissions (60), as well as cigarettes with novel technologies, such as filter capsules to alter the delivery of flavours and/or emissions (61). Tobacco-related products that do not contain tobacco but resemble tobacco products in terms of presentation and mode of use, such as electronic cigarettes/ENDS, shisha pens, herbal products and waterpipe steam stones, have become popular as well. Some of these tobacco-related products contain nicotine, while others do not. For example, ENNDS, which bear a close resemblance to ENDS, do not contain nicotine.

The aim of this chapter is to provide guidance on options for regulating novel, new, and modified TRPs. As indicated in Chapter 1, WHO FCTC obligations apply in respect of all tobacco products, including HTPs. Additionally, countries have adopted different approaches in determining which products they consider to be subject to tobacco regulation. This chapter considers a basic framework for relating novel, new, and modified products to traditional tobacco products. Second, it discusses the importance of surveillance and reporting to identify and track novel, new and modified TRPs. Third, it considers the unique health and population risks of novel, new and modified TRPs and possible approaches to evaluating these products. Recommendations for policy makers are provided based on these considerations and the current state of knowledge regarding these products. It should be kept in mind that regulatory approaches may be different when it comes to the classification or categorization of products and the devices that are used to consume it (e.g. pipe, shisha pen, waterpipe). Therefore it is important to clearly specify the scope of a regulatory framework and the definitions used.

Relevant COP decisions include FCTC/COP7(14) (Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC) which invited WHO (1) to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as heated tobacco products and (2) to identify, in synergy with other WHO FCTC work on implementation/capacity

building, approaches and strategies to build capacity for Parties wishing to monitor market characteristics and trends through registration, licensing or notification, as well as reporting on tobacco products in order to inform policy-making.

## 6.1 WHAT ARE NOVEL, NEW OR MODIFIED TRPs?

Categorization of tobacco products can be useful to determine which regulatory frameworks or provisions apply, and whether new or additional regulation is needed. WHO identifies new or novel products as tobacco products that employ new or unconventional technology, such as vaporization of tobacco into the lungs or menthol pellets in the cigarette filter; products that have been on the market for a limited period of time or are newly introduced in a given country; and/or products which have been or could be marketed with claims of reduced risk (62).

The EU's TPD2 (17) defines novel tobacco products as tobacco products which do not fall into any of the categories defined by TPD2: cigarettes, RYO tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use and placed on the market after 19 May 2014. In addition, TPD2 provided the first comprehensive regulatory framework for ENDS. In the USA, new tobacco products include all products not yet on the market before a certain date, regardless of novelty in their design.

For the purposes of developing a regulatory approach, it may prove useful initially to distinguish new products according to their relative degree of difference from traditional combusted or non-combusted tobacco products. This should not imply that the degree of difference will be directly related to anticipated health risks and/or product toxicity, attractiveness, or addictiveness. Rather, it places a burden of greater regulatory scrutiny on products for which the health risks and related outcomes have the highest degree of uncertainty. Note that there are no clear delineations between the proposed categories below, and policy-makers should consider setting as strict boundaries as possible in developing definitions while considering their specific regulatory framework.

- 1. Novel TRPs.** These include new TRPs and/or new categories of TRPs with a mechanism for delivery that differs from established tobacco products, resulting in significant differences in product content, design, and emissions. Examples may include HTPs and dissolvable tobacco.
- 2. Novel technologies.** These consist of new technologies that are integrated within the design of existing tobacco products with potentially significant changes to product toxicity, addictiveness, or attractiveness. Examples include application of flavour filter capsules or genetically modified tobacco (resulting in e.g. very high/very low nicotine content tobacco) to cigarettes.
- 3. New or modified tobacco products.** These describe any new tobacco product that uses technologies and design that may be considered equivalent to that of other established tobacco products; and/or any minor modification to an existing tobacco product, such as a change in additive composition, tobacco blend, or cigarette paper.

WHO FCTC obligations apply in respect of all tobacco products, including product categories such as HTPs. All products deemed to be legally tobacco products by a country should be subject to appropriate policy and regulatory measures. In the case of novel, new or modified TRPs, it may be necessary or desirable to consider the need for additional regulations addressing the specific challenges posed by these products. For novel TRP (category 1) and novel technology (category 2) products, this may include consideration of the kinds of health claims permissible (if any), or differences relative to other existing tobacco products in how these products may be marketed or sold.

If regulations have already been implemented for existing tobacco products, these may be sufficient to cover new or modified (category 3) tobacco products, or it may be desirable to establish regulatory barriers or require premarket approval before the introduction of any product changes (see Case Study 8). Local or regional context must also be considered: an existing product that is recently introduced or popularized in a country or region (e.g. smokeless tobacco or waterpipe tobacco) may effectively be considered a new or modified product in that country or region, with patterns of use or health risks that may differ significantly from those in the country or region of origin.

## CASE STUDY 8: USA

### AUTHORIZATION REGIMES FOR DIFFERENT PRODUCT CATEGORIES

Under the United States Family Smoking Prevention and Tobacco Control Act, manufacturers must receive an authorization to sell prior to the introduction of any new product to the market, and any new product that is not substantially the same as already existing products (substantial equivalence) is not permitted. Manufacturers must also report all modifications to ingredients, additives, components, and materials (e.g., paper porosity) of current products, recognizing that changes to these components could raise public health questions different to or over that of an existing product (63).

New products which do not meet the necessary criteria for substantial equivalence to an existing product can seek regulatory authorization through other mechanisms. The first, called premarket authorization, is an evaluation to determine whether marketing of the new product is “appropriate for the protection of public health” (64). ENDS are considered under this mechanism. Premarket authorization requires a more comprehensive and thorough assessment of health impact(s) compared to substantial equivalence. Critically, approval is not based on the risks of the product in isolation (considered by itself) but by comparison to and in the context of pre-existing, harmful tobacco products.

A second regulatory mechanism is available to manufacturers seeking to have their products classified as “modified risk tobacco products” (MRTPs), defined as tobacco products that are sold or distributed to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. MRTPs are evaluated in terms of whether modified risk claims are supported by the submitted data (65).

## 6.2 HOW DO YOU IDENTIFY NOVEL, NEW OR MODIFIED TRPS IN YOUR MARKET?

Given the potential health risks of novel, new or modified TRPs, including the possibility that these products can serve as gateways to the use of other harmful tobacco products, it is important for health authorities to closely monitor the introduction and sale of new and novel products in their markets (62). This can be accomplished by ongoing surveillance, as well as requirements for reporting, as described below.

**Surveillance** enables health authorities to be informed in a timely fashion of new developments in the availability or marketing of TRPs, as well as consumer attitudes and behaviour, and prevalence of use. Surveillance can be conducted on a formal basis through development of a single or ongoing survey mechanism by the health authority, or in coordination with universities or other research organizations. Market or sales data may also be available publicly or for purchase at the local or regional level to assess product consumption, or may be required by reporting mechanisms (see below). Informally, surveillance can also include searches of published literature, websites, patent literature, trade journals, and social media. According to WHO TobReg (66), the aim of surveillance should not only be to identify new and novel products but also to assess the likelihood that such products will gain market share.

**Reporting** refers to the direct disclosure by manufacturers of product information, including the contents, design features and emissions of products to the health authority as recommended in accordance with Article 10 of the WHO FCTC (see Chapter 2). Reporting requirements should inform health authorities when new tobacco products have been introduced to the market, and in most cases, should include sufficient information to enable health authorities to determine whether new products are equivalent to other tobacco products on the market, or whether they raise specific questions of content, design, or emissions sufficient to classify them as novel TRPs (category 1) or as introducing novel technologies (category 2). Note that information provided by industry must generally be verified by tobacco industry independent assessors and/or reference laboratories (see Chapter 7). Methods developed and validated by WHO TobLabNet may be suitable for monitoring and regulating the contents and emissions of novel, new or modified TRPs and for some subject to modification, following method assessment.

Given that novel TRPs or products with novel technologies can differ substantially from existing tobacco products, health authorities may want to consider including specific pre-market notification obligations in their reporting requirements. For example, the EU's TPD2 provisions require manufacturers to notify competent authorities six months before a novel tobacco product is placed on the market. The notification must include a detailed description of the product, instructions for its use, information on ingredients and emissions, and available scientific and market studies relevant to the evaluation of its toxicity, addictiveness and attractiveness, and population health impact, such as consumer preferences, risk-benefit and expected impacts on cessation and initiation. Member States may also request additional information or testing, may introduce a system for the authorisation

of these products and may charge proportionate fees for that authorization. Like other tobacco products, novel tobacco products have to comply with the relevant provisions of TPD2. Moreover, promotional elements including health claims are prohibited for novel tobacco products. Data on sales volume are required once the product has been introduced.

For existing products, TPD2 provisions require that industry shall inform Member States if the composition or design of a product is modified in a way that affects the information provided under TPD2, i.e. with regard to their ingredients and emission levels. This applies for instance to modifications to the product composition such as to the filter, paper, tobacco or additives used.

### **6.3 HOW DO YOU EVALUATE NOVEL TRPs AND SO-CALLED REDUCED RISK PRODUCTS?**

If deemed necessary based on market developments (e.g. rapid increase in popularity) or other information, health authorities may decide to evaluate a novel, new or modified TRPs to assess likely health outcomes. However, the degree to which the product differs in design or use from existing tobacco products will increase the need for individual and/or population-based risk assessment. An evaluation may also be necessary to assess whether current regulations are sufficient to address the potential risks posed by the product and/or whether additional measures should be implemented. In most jurisdictions current regulations do not (completely) cover all novel TRPs as some may not fit well in any existing regulatory category. Furthermore, some novel TRPs may have effects or implications that are not encountered with existing tobacco products, such as electrical safety for electronic cigarettes. Thus, it must be determined in each case which aspects of these products could be potentially regulated to benefit individual and public health.

Many of the priorities in assessing novel TRPs will mirror those applied to evaluation of existing tobacco products: their relative and absolute toxicity, their attractiveness among specific target groups, and their potential to support addiction. These aspects of the product will need to be considered not only with respect to the product itself, but also in relation to the pre-existing tobacco products market, considering potential confounding factors such as recruitment of new users or user groups, potential for relapse among former tobacco users, and dual (or poly) use of both novel TRPs and existing tobacco products. For instance, whereas electronic cigarettes/ENDS are generally considered to be less harmful for a smoker than a tobacco cigarette, effects at the population level are not yet clear.

On the one hand, electronic cigarette/ENDS use is increasing among young people in some high-income countries, such as the USA (67), and some research suggests they may serve as a gateway to the use of other tobacco products (67, 68). On the other hand, studies indicate that they may be an effective smoking cessation tool (69, 70). Unfortunately, sufficient information is often not available to make a com-

plete assessment of the impact on public health. These uncertainties, together with country-specific circumstances and political views, have led different countries to pursue opposing policy options ranging from an outright ban on their sale and/or importation (e.g. in Brazil, Singapore, Thailand, Uruguay and Venezuela (Bolivarian Republic of)) to promotion as a tool for lowering smoking prevalence.

Many novel TRPs have been marketed and/or perceived as harm reduction or reduced risk products despite a lack of independent scientific evidence. Implicit or explicit health claims may warrant more stringent evaluation insofar as health claims may themselves be used to increase product attractiveness and minimize the health concerns that would act as barriers to use.

Comprehensive assessment of toxicity generally encompasses measures of toxicants in content and emissions, measures of biomarkers of exposure, measures of biomarkers of effect (i.e. disease outcomes), and measures of use and perception in clinical trials. For example, guidelines for suitable test paradigms and specific tests to inform on additive-induced toxicity, addictiveness, and attractiveness can be found in the EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) report (71) and in other scientific advisories (72, 73, 74). These guidelines and testing paradigms are not only limited to assessing individual compounds but are also adaptable to assess the contents and emissions of TRPs. For regulations specifically aimed at nicotine-containing products, there is a risk that products may appear on the market with nicotine-analogues or other addictive compounds. WHO TobReg has also published detailed recommendations on methods and protocols necessary to assess novel TRPs, including post-market surveillance and monitoring of design features, contents and emissions of novel products over time (66). Data collection that may prove necessary to support the evaluation of novel TRPs include the following:

- description of the product (composition, physical parameters, design features, package);
- marketing and promotion;
- cost relative to that of other tobacco products;
- awareness and perception of the product;
- prevalence and patterns of use, including use with other products;
- reasons for use;
- uptake by young people and whether uptake leads to use of other tobacco products;
- groups targeted for use, such as young people, women and populations with co-morbid medical and mental disorders;
- development and severity of dependence;
- behavioural measures (e.g. topography); and
- exposure to nicotine and/or other addictive compounds.

Unfortunately, sufficient information may not be available to make a full assessment of all factors at the individual and population level. Modelling of factors using optimistic and pessimistic scenarios could be a useful tool when faced with many unknowns (75). Recent efforts to assess relative risks of electronic cigarettes/ENDS and HTPs, as compared with tobacco cigarettes, have been based on summations



of cancer risk indices of smoke emissions (76), simple counting of the number of emissions in levels higher than a guideline level (77), or expert judgement using multi-criteria decision conferencing (78).

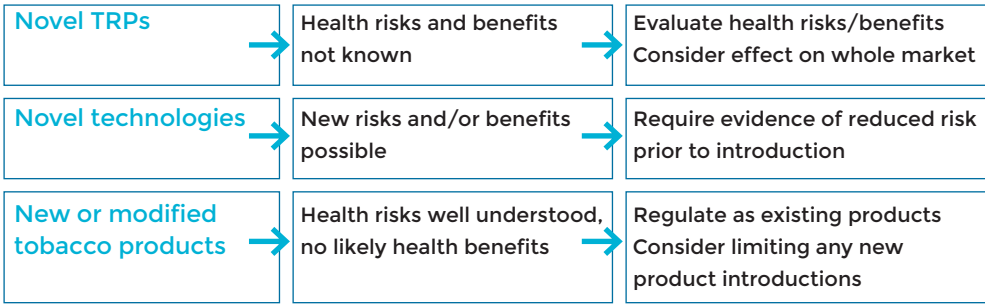
## 6.4 HOW DO YOU REGULATE NOVEL, NEW AND MODIFIED TRPS?

Regulation of tobacco products as described in Articles 9 and 10 of the WHO FCTC extends to all tobacco containing products, including all novel tobacco products, and those tobacco products marketed by the industry as reduced risk. WHO TobReg further advises that all TRPs, including tobacco-containing and non-tobacco-containing products, that could aid or limit smoking cessation, lead to initiation and addiction, or result in maintenance of smoking through dual or poly use, should be regulated to maximize any benefits and minimize harm (66). Health authorities will need to collect data, adopt evaluation tools, and consult independent evaluators and researchers to make science-based decisions on the risks of novel, new and modified TRPs, and assess potential effects on toxicity, addictiveness, and attractiveness for the individual users and the population. The availability of global data on products can assist with this evaluation, although product and social or contextual differences may exist across countries or regions, which must be taken into consideration when assessing these products.

Countries should consider requiring notification to the health authority of any TRPs intended to be sold or marketed. This will allow the health authority to be aware of any form of new or novel TRP that is to be placed in the market, enable surveillance and control over such products and the setting of a national database on the availability of TRPs for future regulatory settings. Countries may consider requiring a registration fee to cover the cost of the notification.

Appropriate regulatory strategies for novel, new or modified TRPs will differ based on evaluation of their potential risks and benefits. The classification of products according to categories of novel TRPs (category 1), novel technologies (category 2), and modified tobacco products (category 3) provides an initial framework for developing a regulatory approach (see Fig. 6). New products with minor modifications, such as the use of additive(s) or blend formulations, are unlikely to have significant health benefits, and should be regulated in a manner consistent with other existing products, or potentially restricted through defined regulatory hurdles as in the United States. Existing products incorporating novel technologies may have either risks or benefits, or both. For example, flavour capsules are being used to increase the attractiveness of cigarettes, whereas cigarettes made from very low nicotine content tobacco may potentially support a reduction in population harm by reducing the addictiveness of products. Thus, products and technologies will need to be reviewed on a case-by-case basis and regulated accordingly.

**Fig. 6. Regulatory strategies based on proposed classifications of new, novel, and modified tobacco and related products**



Novel TRPs (category 1) represent the greatest uncertainty with respect to potential risks and benefits, and the greatest challenge with respect to evaluation. For these reasons, approaches to regulating novel TRPs have differed widely. Between these extremes are a range of potential options, such as clearly defined channels to market entry, or product access restricted to specific target groups.

It is important to consider options for the regulation of novel TRPs at an early stage, even if the products have not achieved a high market share and regulation does not yet seem to warrant a high priority, since it cannot be easily predicted which products will gain significant market share or impact the market, as for example in the case of the shisha pen. If a novel TRP is more toxic, attractive, or addictive compared with existing products, and has no obvious public health benefits, parties should consider regulations, restrictions or an outright ban on the introduction of these products. Determination of what and how to regulate will be dependent on the priorities and situation of the regulating country.

For countries where novel TRPs are permitted, health authorities should at a minimum:

- require mandatory notification of any novel tobacco products prior its marketing/retail at local market;
- assess the potential effects of the product on toxicity, addictiveness, and attractiveness for individual users and the population (data delivered by industry via reporting obligations can be helpful in this respect, but independent verification is needed);
- implement validated WHO TobLabNet methods for monitoring and regulating the contents, design features and emissions of these products;
- levy costs on the tobacco industry for registration of products and of verification measurements, analysis and publication of data to tobacco industry;
- conduct post-market monitoring of use and health outcomes, and re-evaluate with the possibility to adapt legislation or ban the product if new health concerns are raised;
- provide adequate risk communication messages to the public, while avoiding the trap of increasing public knowledge of the products on behalf of the tobacco manufacturers;
- consider the possibility of message diversification in the case of potential



- harm reduction products, and/or legislation, in line with the fact that nicotine is delivered through products that represent a continuum of risk, and is most harmful when delivered through combusted products (21), while avoiding creating an overall impression that other tobacco products are without risk; and
- consider the circumvention potential of such products: allowing the use of these products in places where smoking is prohibited may undermine tobacco control policies aimed at de-normalizing tobacco consumption, as well as protecting against exposure to tobacco consumption.

As is mentioned above, WHO FCTC obligations apply in respect of all tobacco products, including HTPs. This means that the full range of WHO FCTC legal obligations are applicable to HTPs.

In the context of ENDS, WHO recommends that governments:

- prohibit or regulate ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;
- prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval;
- prohibit the use of ENDS in public enclosed spaces, especially where smoking is banned effectively restrict advertising, promotion and sponsorship of ENDS;
- protect regulators from vested commercial interests;
- effectively regulate product design and information;
- use health warnings;
- strengthen existing tobacco surveillance and monitoring systems; and
- prohibit sale of ENDS to minors.

Note that in some cases, regulations may need to be clarified to include both the device and its intended filler, e.g. for an electronic cigarette/ENDS and its liquids, for an HTP and its fillers, such as heat sticks, and for a waterpipe and its tobacco or herbal filling. Regulation of devices may include heating elements, such as waterpipe coals, functional elements such as the battery, wick, and compartment, and aspects of physical appearance such as colour or shape. Regulation of fillers could extend to their composition, nicotine content, and flavour, as well as package, warning labels, and other marketing. Given that many different types of fillers can be used in a single device, defining product emissions may present a regulatory challenge. For waterpipe, the many different types of coals that can be used present a similar problem. Clear regulatory distinctions between products and categories of products and clear definitions of products and components are critical to support effective regulation.

In regulating novel TRPs and other new products, health authorities should be prepared for resistance from the tobacco industry. If such regulations are extended to non-tobacco products such as electronic cigarettes/ENDS, the scope of resistance may expand to new action groups, and indeed, associations of electronic cigarette/ENDS users are already active in several countries. Smuggling and/or illicit sale of novel TRPs following restrictions or bans may prove similar to that of traditional tobacco products.

## CASE STUDY 9: GERMANY

### SUCCESSFUL BAN ON MENTHOL CAPSULES BY DEMONSTRATING THAT CAPSULES INCREASE PRODUCT ATTRACTIVENESS

Flavour capsules are a recent tobacco industry technology in which capsules containing a liquid flavouring agent (most commonly menthol) are embedded in the cigarette filter. A smoker crushes the capsule to release the flavour which is then inhaled together with the smoke.

In 2012, the German Cancer Research Centre (GCRC) issued a comprehensive document on the attractiveness of menthol capsules in cigarette filter (79), including data demonstrating that the industry uses the menthol released in flavour capsules to mask the harshness of tobacco, facilitate inhalation of smoke, and give an overall impression of reduced harm, and that the use of menthol cigarettes is common among new smokers. The GCRC recommended maintaining the prohibition of capsuled tobacco products (menthol and others) in Germany, and the banning of ingredients that increase the attractiveness of tobacco products. These provisions were implemented within the context of TPD1.

In the same year, a tobacco company filed an application to sell cigarettes with menthol capsules with the relevant health authority, the Federal Office of Consumer Protection and Food Safety. Following review, the authority rejected the application on public health grounds. The tobacco company appealed this decision, which was dismissed by the Administrative Court in September 2012 (80).

In its decision, the Court stated that “even in the absence to date of studies showing that the menthol contained in capsule cigarettes further increases the health hazards of the individual cigarette, existing findings do suggest that cigarettes equipped with flavour capsules are more hazardous than conventional cigarettes. Marketing of the cigarette product developed by the claimant violates the principles of tobacco control laid down, among others, in the WHO FCTC. According to the convention, the attractiveness of tobacco products should not be further increased by novel technologies.” Since introducing cigarettes with flavour capsules makes smoking more attractive, the court confirmed the Federal Office’s decision to reject the application for menthol capsules.

The use of flavourings in any components of tobacco products, such as capsules, has been prohibited in the EU under TPD2.

## Chapter 7.

# TESTING AND DISCLOSURE

Articles 9 and 10 of the WHO FCTC (1) require Parties to adopt standards that govern tobacco product testing and the disclosure of information on tobacco product content and emissions. The disclosure of product information takes two forms:

- the disclosure of information by manufacturers to health authorities; and
- the disclosure of information from health authorities to the public.

Product testing is used to generate the data necessary to support both forms of disclosure. Further elaboration of these requirements, as defined in the Partial Guidelines (4, 27), is provided in Chapter 2. Tobacco product testing and disclosure measures provide health authorities with knowledge that can be used to evaluate current policies and to develop and implement new or expanded policies, activities and regulations. This knowledge may also be used to inform the public, in a comprehensible manner, about the properties, components, and associated or potential risks or effects of the products, including the addictive nature of tobacco products and the harmful effects of exposure to and use of these products. Thus, the overall aim of testing and disclosure is to assist tobacco control efforts that advance public health.

This chapter is intended to assist health authorities by outlining what testing and disclosure measures may entail, raising practical considerations for implementation, and identifying ways to offset costs. Tobacco product testing and disclosure are of greatest benefit to health authorities when they are made an integral component of a comprehensive tobacco control strategy, directly supporting clearly identified policy objectives, and with adequate resources to support defined aims.

### 7.1 WHAT IS TOBACCO PRODUCT TESTING?

Some information, which health authorities request from manufacturers on tobacco products, can only be obtained by laboratory testing. Laboratory product testing is a repetitive examination of the chemical substances, physical parameters, and other measurable characteristics of the product, relying on standardized methods. In some cases laboratory testing may require little or no specialized knowledge or equipment (e.g. measures of weight, length, circumference), while other testing may be costly, labour intensive and/or require significant expertise.

Laboratory testing is not the only means to obtain information about tobacco products. Some types of information, such as sales data, can be provided by the industry

without prescribed testing. Disclosure of ingredient formulas, design specifications, performance or quality assurance standards used to guide manufacturing, or information provided by suppliers (e.g. paper, adhesive, or flavour manufacturers) can provide valuable information about the composition of the product and should also be obtainable without the need for testing. An important limitation is that this information relates to the production of the product and not to the product as it is consumed. Processes, such as fermentation, evaporation, heat treatment, or chemical reaction may significantly alter product ingredients between the time they are added and the time the product is ready for sale. In the case of combusted products, this information is further limited by the changes that occur during combustion and generation of smoke emissions.

## Who conducts testing?

The burden of testing to support the disclosure of information on product content, design and emissions should fall on manufacturers. This means that manufacturers should be required to fund testing, whether conducted by the manufacturer or a contracted laboratory. Further recommendations by the COP to the WHO FCTC (27) on requirements for the laboratory responsible for testing are described in Chapter 2. Regulations on testing should empower the health authority to specify the form and manner appropriate for submission of data (see below), and should provide sufficient flexibility to alter the scope of testing and disclosure requirements as scientific research is advanced.

In addition to mandated disclosure testing as described above, additional testing can be performed by health authorities using their own laboratory or an independent (contracted) and duly accredited laboratory. This route may be adopted to verify the data provided by industry (see below), or when the health authority chooses to collect information that falls outside the testing requirements imposed on the industry by regulations.

## Frequency and scope of testing

Countries should mandate the reporting of testing results at established intervals, for example every year, on all products marketed within a country, including those manufactured locally, imported and where relevant, exported. This will equip health authorities with information that can be used to effectively support tobacco control and regulation in that country; for example, by identification of products with significant changes in contents, design or emissions or that raise concerns with respect to levels of toxicants or product additives.

Compliance or verification testing should be conducted separately on a random sample of brands by the health authority's own or an independent (contracted) and duly accredited laboratory, and can be less frequent. The purpose of verification testing is to ensure the reliability of data provided by industry (see below).

## What to test?

Laboratory testing should encompass, but is not limited to, aspects of tobacco product contents, design features, and emissions that have been identified as affecting product toxicity, attractiveness, or addictiveness. Given that there are numerous toxic, attractive and addictive substances contained in tobacco products and their emissions, health authorities may wish to prioritize substances that pose clear health risks depending on the type of tobacco products found in the market. For example, several national authorities require testing of the nicotine content or emission of tobacco products due to its primary role in addiction.

WHO TobReg has provided guidance on priority substances for testing and monitoring, as described below. With respect to the contents and emissions on cigarette tobacco, COP3 (81) shortlisted the following chemicals and toxicants as priorities.

### Contents

- Nicotine
- Ammonia
- Humectants (glycerol, propylene glycol and triethylene glycol).

### Emissions

- Nicotine
- Carbon monoxide
- Benzo[a]pyrene
- Aldehydes (formaldehyde, acetaldehyde and acrolein)
- Volatile organics (1,3-butadiene and benzene).

Methods for the above priority chemicals and toxicants, identified as WHO TobLab-Net Standard Operating Procedures (SOP), have been validated by WHO TobLabNet and are available on the WHO/TFI website (82).

At COP6 (62), an expanded list of 39 toxicants was identified for testing in tobacco products as provided in the following table (38 toxicants were noted in the original report, with arsenic later added).

Acetaldehyde	Acetone	Acrolein	Acrylonitrile
1- Aminonaphthalene	2-Aminonaphthalene	3-Aminobiphenyl	4-Aminobiphenyl
Ammonia	Arsenic	Benzene	Benzo[a]pyrene
1,3 Butadiene	Butyraldehyde	Cadmium	Carbon monoxide
Catechol	m-+p-Cresol	o-Cresol	Crotonaldehyde
Formaldehyde	Hydrogen cyanide	Hydroquinone	Isoprene

Lead	Mercury	Nicotine	Nitric oxide
N- nitrosoanabasine	N- nitrosoanatabine	4-(methylnitroso- mino)-1-(3-pyridyl) -1-butanone (NNK)	N'- nitrosornicotine (NNN)
Nitric oxide (NO)	Phenol	Propionaldehyde	Pyridine
Quinoline	Resorcinol	Toluene	

Methods for the expanded list of toxicants are available on the WHO/TFI website (82) and further discussion can be found in the fifth report of the WHO TobReg (66).

## Addressing the reliability of laboratory results

Accuracy and precision of laboratory results submitted by industry is of importance to health authorities. To this end, the Partial Guidelines on Articles 9 and 10 of the WHO FCTC recommend that laboratories used by the industry for the purposes of disclosure to health authorities be accredited in accordance with International Organization for Standardization (ISO) Standard 17025 (General requirements for the competence of testing and calibration laboratories), by a recognized accreditation body, usually the national accreditation body of the country in question. To be accredited, these laboratories must have trained and competent staff that can follow procedures that are sensitive, selective and accurate. The analytical methods used for testing products must also be within the laboratory's scope of accreditation. For example, if a laboratory is accredited to test compound A, it does not necessarily mean that it can competently test compound B as this would fall outside the scope of the laboratory's accreditation.

In cases where laboratory accreditation is not an available option, the health authority may consider verifying the data collected from industry laboratories using confirmatory testing conducted by its own (government) laboratory, or by a tobacco industry independent (contracted) laboratory. For this task, authorities may also wish to contract only with tobacco industry independent laboratories that are accredited to ISO 17025 Standard or its equivalent.

## Sampling and storage of tobacco products

Regulations for testing should include a provision setting out the sampling procedure, the number of products to be sampled and the frequency of sampling. For example, samples could be collected from a range of manufacturers, importers or retailers to ensure that the product tested is representative of the product available and in a manner that reflects the domestic tobacco market structure. In addition, rules should be adopted about the storage and preparation of tobacco products for testing. This is important as storage conditions can result in changes in product constituents, such as tobacco-specific nitrosamines (5).

## Infrastructure for the collection and evaluation of data

Effective disclosure requires development of an infrastructure capable of maintaining and evaluating the data received. To facilitate disclosure, health authorities should articulate standard reporting and submission procedures that facilitate a streamlined data collection process and allow for comparisons across brands and regions and over time. Electronic data collection is recommended and the system for data collection should be designed to facilitate both validation and analysis. The manufacturer should submit an attestation to the validity of the data and should be held accountable if the data is found to be unreliable, incomplete or inaccurate.

### 7.2 WHY IS IT IMPORTANT TO TEST TOBACCO PRODUCTS?

Tobacco product testing and disclosure enable health authorities to evaluate compliance with legislation, to build intelligence on products, to monitor products and product changes, to assess the effects of regulation or the effectiveness of testing/disclosure requirements and to inform future regulation. Thus, testing and disclosure provide support for many other forms of product regulation. Similarly, regulatory compliance testing applies to all consumer products, and tobacco products should not be exempted from this approach.

#### Monitoring the market

The results of industry testing and disclosure (i.e. information about products) can inform authorities about existing and new health risks and support the development or revision of regulations, by:

- identifying and monitoring products on the domestic market and changes in the market such as the introduction of new product styles or categories;
- identifying high risk products and supporting the development of product standards; and
- supporting comparisons of domestic data with global or published product data to identify outliers or areas of concern with respect to product toxicity, attractiveness or dependence inducement.

Results may also help authorities assess tobacco industry claims about their products, evaluate the public health impact of regulations, and shape effective public messaging about the addictiveness and toxicity of tobacco products.

#### Monitoring for compliance

Health authorities may wish to test samples of tobacco products for compliance with a product standard, where such a standard has been adopted. For example,

where a country has adopted standards that prohibit the use of menthol (a flavouring substance), the authority may put in place a programme to monitor industry compliance with that standard. This will enable the authority to act quickly to remove products from the market that are not compliant with regulation. The Partial Guidelines on Articles 9 and 10 of the WHO FCTC recommend that laboratories used for compliance monitoring purposes should be either government laboratories or independent (contracted) laboratories that are not owned or controlled – either directly or indirectly – by the tobacco industry. Further, such laboratories should be accredited as detailed above.

## Testing for research purposes

Testing for research purposes is sometimes carried out by health authorities to increase their understanding of the composition of tobacco products or of how products behave under certain conditions. This research may also be used to inform and/or educate the public regarding potential health concerns. Health authorities may choose to use their own laboratory or a tobacco industry independent (contracted) laboratory so they can look at a specific research question, such as the introduction of filter capsules into the market by a tobacco company. Research by health authorities can also extend to population health surveillance, and/or *in vitro* testing or human subjects (e.g. biomonitoring). These forms of testing will require additional knowledge, capacity and resources.

## 7.3 HOW SHOULD TOBACCO PRODUCT INFORMATION BE REPORTED TO THE PUBLIC?

Disclosing information to the public about the nature of tobacco products, including their toxic constituents and emissions, can help raise awareness of the health consequences, toxicity, attractiveness, the addictive nature of the products and the mortal threat posed by tobacco use and exposure to tobacco emissions. Caution should be exercised as inappropriate or ineffective disclosure could be a source of confusion and result in more harm to public health. An example is the use of TNCO labelling on cigarette packages, which have been misinterpreted as describing relative risk among products, as described in Case Study 7.

Disclosure to the public does not only mean the release of information. Rather, it means that information should be structured in such a way that the public can understand the information disclosed and make the best use of it. An excellent example can be found on the United States FDA web page: Chemicals in Cigarettes: From Plant to Product to Puff. (83) It is suggested that health authorities consult with other countries and experts to identify potential challenges in reporting information to the public and identify best practices regarding dissemination of reported data and health/risk communication.



## 7.4 WHAT RESOURCES DO YOU NEED TO SUPPORT TOBACCO PRODUCT TESTING?

Requiring the tobacco industry to test tobacco products as a condition of sale should provide reliable and comprehensive information on the products' contents, design features and emissions, at a low cost to government.

At the same time, operating a testing and disclosure programme may require that new infrastructure be set up to identify the specific testing and disclosure measures to implement, and to receive the reports and oversee their quality, completeness and accuracy. Where industry violates the rules, there must be capacity to request compliance or penalties for non-compliance. Enforcement action may also be needed. Operating such a programme may also require the allocation of significant resources by health authorities.

To reduce the burden on governments, costs related to testing and disclosure could be charged to the tobacco industry through a cost-recovery mechanism.

Some options for funding sources include:

- designated tobacco taxes
- tobacco manufacturing and/or importing licensing fees
- tobacco product registration fees
- licensing of tobacco distributors and/or retailers
- non-compliance fees levied on the tobacco industry and retailers
- annual tobacco surveillance fees (tobacco industry and retailers).

Comprehensive information on available resources and cost-recovery mechanisms, as well as detailed technical information on the steps to develop and make effective use of a country's own tobacco product testing capacity, can be found in: *Tobacco product regulation – building laboratory testing capacity (5)*. This is a separate report which complements the tobacco product regulation handbook, providing an overview of laboratory testing including:

- why testing is important
- what to test
- who should test
- where to test
- how to test
- when to test
- how to use generated data
- available resources to support countries.

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## Annex 1.

# PROVISIONS OF THE EU TOBACCO PRODUCTS DIRECTIVE (TPD2)

## LABELLING AND PACKAGING

### 1.1 Large mandatory pictorial health warnings

Graphic health warnings with photos, text and cessation information now cover 65% of the front and back of the packs for cigarette, roll-your-own tobacco (RYO) and waterpipe tobacco packs. Depicting the social and health impact of smoking, the warnings are designed to discourage people from smoking or encourage them to quit. The warnings, for which the European Union holds the copyright, are grouped into three sets of 14 each, to be rotated every year, to ensure that they retain their impact for as long as possible.

While the new rules mean that health warnings will cover a substantial part of the total surface of cigarette packages, a certain space will remain available for branding. TPD2 specifically allows Member States to introduce further requirements relating to standardisation of packaging – or plain packaging – where they are justified on grounds of public health, are proportionate and do not lead to discrimination or hidden barriers to trade between Member States.

#### **Labelling of other tobacco products**

Whereas the EU Directive covers all tobacco products, Member States have some more discretion when it comes to labelling rules for tobacco products for smoking not currently used by vulnerable population groups in significant quantities such as pipe tobacco, cigars, and cigarillos. While Member States could choose to exempt these products from stringent labelling rules, e.g. combined health warnings, they are obliged to ensure that these products carry a general warning and an additional text warning of at least 30%.

Smokeless tobacco products have to display a specific health warning on the two largest surfaces of the pack, each covering at least 30% (“This tobacco product damages your health and is addictive”).

As in the former Directive, specific rules apply for the placement and size of all warnings.



### **General health warning and replacement of TNCO labelling by an information message**

The tar, nicotine and carbon monoxide (TNCO) labelling on cigarettes and RYO tobacco, mandatory under TPD1, was replaced with an information message that informs consumers that “Tobacco smoke contains over 70 substances known to cause cancer”. This provision was chosen in line with WHO FCTC Article 11 and the guidelines on its implementation. Research had shown that TNCO labelling is misleading to consumers as it makes them believe that some products are less risky to their health than others. The new information message more accurately reflects the true health consequences of smoking and complements the general health warning “Smoking kills”/”Smoking kills – quit now”. However, the upper limits for emission for TNCO (measurement according to ISO standards 4387 for tar, 10 315 for nicotine, and 8454 for carbon monoxide) have been kept to ensure consistency of permissible products on the EU market. Furthermore, the Directive foresees the possibility to adapt emission measurement methods and limits for TNCO and allows for setting maximum emission levels for other substances as well as in other tobacco products, based on scientific and technical developments or internationally agreed standards. The information message and the general health warning each cover 50% of the surface area on which they are printed. This surface depends on the type of packaging used.

### **No more promotional or misleading packages**

The TPD entails provisions to reduce the attractiveness of products and increase the noticeability of the health information. Cigarette packs must have a cuboid shape to ensure visibility of the combined health warnings. Certain package types appealing to young people, such as packs containing less than 20 cigarettes and lipstick-style slim packs are no longer allowed. Furthermore, promotional or misleading features or elements are banned as well as references to lifestyle benefits, taste or flavourings. Special offers and suggestions that a particular product is less harmful than another, or has improved biodegradability or other environmental advantages, are no longer possible.

## **1.2 Ingredient Reporting and Regulation**

### **Ban on cigarettes and RYO with characterizing flavours**

Cigarettes and RYO tobacco products may no longer have characterizing flavours such as menthol, vanilla or candy that mask the taste and smell of tobacco. TPD2 aims at avoiding unjustified differences of treatment between different types of flavoured cigarettes, in light of the experience gained by other jurisdictions (see e.g. Chapter 2). However, it has been agreed that products with a characterizing flavour with a higher sales volume (more than 3% EU wide) should be phased out over an extended time period (until 19 May 2020) to allow consumers adequate time to switch to other products.

A procedure for determining whether a tobacco product has a characterizing flavour, and an independent advisory panel supported by a technical group of chemical and sensory assessors, has been set up to assist the Commission and Member States in

the decision-making process. The exemption of these provisions for other tobacco products may be withdrawn if there is a substantial change in the sales volume and use of these products in young people.

#### **Ban on additives or products with certain properties**

Certain additives that are associated with certain positive properties (e.g. health benefits, reduced risks, energy, vitality), that have colouring properties or that facilitate inhalation or nicotine uptake are prohibited. Likewise, products containing additives which increase the toxicity or addictiveness of a tobacco product are banned.

#### **Ban on flavourings in certain components of tobacco products**

Tobacco products shall not contain flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine. This provision aims at ensuring that innovative and attractive design features likely to increase experimentation and consumption are prohibited.

#### **Mandatory electronic reporting on ingredients, emissions and sales data**

To gather more information on the ingredients contained in tobacco products and their effects on health and addiction, manufacturers and importers of tobacco products are required to report on ingredients in all products they place on the EU market through a standardized electronic format, the EU-CEG, as well as information on certain emissions. Relevant toxicological data shall also be submitted. Furthermore, manufacturers and importers are required to report on marketing studies and sales data.

#### **Priority additives**

Certain frequently used substances (priority additives) where initial indications have suggested that they contribute to the toxicity, addictiveness and/or result in characterizing flavours in cigarettes and RYO tobacco are subject to more detailed reporting requirements. A first list of such additives has been developed as part of the implementation of TPD2.

## **1.3 E-cigarettes/ENDS**

#### **Safety and quality requirements**

TPD2 introduces for the first time a regulatory framework for e-cigarettes. This includes certain safety and quality requirements for e-cigarettes and for refill containers containing nicotine. Inter alia, the Directive sets maximum nicotine concentrations and maximum volumes for cartridges, tanks and nicotine liquid containers. E-cigarettes should be child-resistant and tamper proof, and have a mechanism that ensures refilling without spillage to protect consumers. E-cigarette ingredients must be of high purity and e-cigarettes should deliver the nicotine doses at consistent levels under normal condition of use.

#### **Packaging and labelling rules**

Mandatory health warnings for e-cigarettes and refill containers advise consumers



that e-cigarettes contain nicotine and should not be used by non-smokers. Packaging must also include a list of all ingredients contained in the product, information on the product's nicotine content and a leaflet setting out instructions for use and information on adverse effects, risk groups and addictiveness and toxicity. Furthermore, promotional elements are not allowed on e-cigarette and refill container packaging, and cross-border advertising as well as promotion is prohibited.

### **Notification and monitoring**

As e-cigarettes are still a relatively new product for which evidence is only starting to emerge, the Directive lays down notification and monitoring requirements for manufacturers and importers, Member States as well as the Commission (Chapter 5). E-cigarette manufacturers must submit a prior notification (six months) to Member States on all products they intend to place on the market, including information on ingredients, emissions and toxicological data. They must report annually on sales volumes, consumer preferences and trends. Member State authorities will monitor the market for any evidence that e-cigarettes lead to nicotine addiction or to tobacco consumption, especially in young people and non-smokers.

## **1.4 Cross-border distance sales**

The Directive allows individual Member States to prohibit cross-border distance sales, which give consumers – including the very young – access to products that do not comply with the Directive. Should an EU country choose this option, the retail outlets in question cannot supply their products to consumers located in that country. If a Member State does not ban such sales, retail outlets must register with the competent authorities and must notify their activity prior to the first sale, both in the country where they are located (if within the EU), and in the country where they plan to sell their products.

Member States shall also ensure an age-verification system to ensure that tobacco products are not sold to children and adolescents.

## **1.5 Novel tobacco products**

TPD2 contains provisions on novel tobacco products, i.e. tobacco products which do not fall into certain established tobacco product categories and were placed on the market after 19 May 2014. Manufacturers/importers of novel tobacco products must submit a prior notification (six months) to Member States where they intend to place such a product on the national market. The notification shall be accompanied by a detailed description of the product and its use, information on ingredients and emissions as well as scientific data, studies and reports on toxicity, addictiveness and attractiveness, consumer preferences, risk-benefit and expected impacts on cessation and initiation. Member States may require further data and may introduce a system for the authorisation of these products.

Like other tobacco products, novel tobacco products have to comply with the relevant provisions of TPD2. Which of these provisions apply depends on whether those

products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking. In either case, promotional elements including health claims are prohibited for novel tobacco products.

## 1.6 Oral tobacco

The ban of oral tobacco (*snus*) has been maintained in TPD2. It has been banned in the EU since 1992. But even before that date, a number of Member States had banned the product, taking into account its significant growth potential and attractiveness for young people. Sweden has an exemption under its Accession Treaty, provided it ensures that the product is not sold outside Sweden.

## 1.7 Herbal products

Herbal products for smoking, which are derived from plants, herbs or fruits but contain no tobacco, are subject to reporting obligations regarding their composition. They also need to display a specific health warning on the front and back of the pack.

## 1.8 Measures to combat illicit trade

New measures intended to combat the illegal trade in tobacco products include EU-wide systems for tobacco traceability and security features. The two systems should help the law enforcement bodies, the national authorities and consumers in detecting illicit products more efficiently. The measures are expected to limit accessibility of artificially cheap, non-TPD2 compliant tobacco products to vulnerable consumer groups such as the young. This should in turn lead to further lowering of the prevalence rates in terms of both of new initiation and quitting rates. In addition, the system should help in shifting a part of the demand for currently illicit tobacco to legal sale channels and hence assist Member States in restoring lost revenues.

These measures will be applicable for cigarettes and roll-your-own tobacco in 2019 and to for tobacco products other than cigarettes and roll-your-own tobacco in 2024. Secondary legislation laying down the technical standards necessary for these systems to become fully operational was adopted by the Commission on 15 December 2017.

## 1.9 Other considerations

Member States have the right to maintain or introduce further requirements in relation to the standardisation of the packaging of tobacco products. Furthermore, they may prohibit a certain category of tobacco and related products on grounds relating to the specific situation in that Member State. Any such provisions need to be also justified by the need to protect public health, should be proportionate and should not lead to discrimination or trade restrictions between Member States. Therefore, Member States have to notify the Commission and provide justification for these measures.



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