TOBACCO PRODUCT REGULATION


1. INTRODUCTION

Until now, discussion on effective policies to limit ill health due to smoking has focused largely on strategies to influence smoking behaviour within the population. Tobacco product modification strategies represent a different approach aimed at ways to make the product less toxic to consumers.

There have been some successes with regulating the marketing and sale of tobacco products in Europe as a result of European Union (EU) Directives and Member State legislation. However, measures to regulate the toxicity of the cigarette itself have been limited and tobacco remains one of the least regulated consumer products in the world. Tobacco manufacturers are largely free to introduce new products onto the EU market at any time they choose and there is very little information available about the characteristics of cigarettes and most other tobacco products available in the EU.

This chapter aims to set out the state of scientific knowledge in the area of tobacco products regulation and to propose new approaches to be considered by national or EU policy makers. In doing so, it draws on a number of other reviews recently published1, 2, 3 and a set of recommendations and principles produced by the World Health Organization’s Study Group on Tobacco Product Regulation (WHO TobReg; formerly known as the WHO’s Scientific Advisory Committee on Tobacco Product Regulation, WHO SACTOB)4, 5, 6, 7, 8.

2. TOBACCO PRODUCT REGULATION

2.1 General principles

Tobacco product modification and harm reduction are subjects of some controversy amongst tobacco-control advocates. There are valid concerns that resources spent devising, implementing and monitoring product regulation strategies could detract from the use of proven tobacco-control strategies (as described in Chapter 4). However, these concerns should not result in regulatory inaction. There is widespread consensus amongst tobacco-control experts that some form of government regulation is needed for tobacco products9, if only to ensure that there is no increase in their toxicity. The EU has a history of trying to make the product less harmful and therefore there is an obligation on the EU to continue its efforts in this direction as it has already exerted its competence in certain areas which may make it more difficult for Member States to implement their own strategies.

Whilst there is an obligation on regulators and producers to reduce the harmfulness of tobacco use as much as possible, it is critically important that product regulation does not detract attention from other essential components of tobacco control aimed at encouraging smokers to stop, protecting non-smokers and preventing young people taking up smoking. Communications about the health risks of various tobacco products and any modifications made to them, which could affect the behaviour of smokers, therefore need to be under strict regulatory control.
Tobacco products are highly engineered and sophisticated nicotine delivery devices. As stated in Chapter 1, this was recognised by the tobacco industry over 40 years ago, and only more recently by the tobacco-control community. Tobacco product regulations must, therefore, take into account the fundamental role nicotine plays in tobacco use. Furthermore, many features have been manipulated to increase the appeal of tobacco products to the consumer and are known to influence both toxicity and addictive potential. It is therefore unlikely that any single test or measure can be used on its own to regulate the harmfulness and addictiveness of tobacco products.

Currently, the cigarette is the dominant form of nicotine delivery system in Europe. In recent years, there has been a proliferation of novel tobacco products launched onto the USA market with many more nicotine delivery devices in development. These products are likely to reach the EU very soon. The novel products include cigarettes with reduced concentrations of tobacco specific nitrosamines (see below), devices heating rather than burning tobacco and smokeless tobacco products. There is currently no regulatory framework within which these products can be meaningfully assessed. Therefore, new regulations need to examine not just cigarettes, but all nicotine delivering products across the range of delivery systems including therapeutic nicotine replacement therapies which are currently the least harmful forms but which are strictly regulated by medicines regulators.

3. EXISTING TOBACCO PRODUCT REGULATION

As stated earlier, the objective of the regulation of tobacco products is to make them less toxic to the consumer. Since the early 1990s regulations in the EU have focused mainly on lowering tar yields. This was based on the belief that tar was the principle carcinogenic and toxic component of cigarettes (see also Chapter 3). It was argued that reducing tar yields would reduce the toxicity of cigarettes and, hence, the mortality and morbidity associated with smoking. This strategy was implemented earlier in some Member States, for example, in the UK it was first implemented in the 1970s.

The tar reduction strategy was further refined and extended by the Recommendations of the Cancer Experts which were adopted by the Helsinki European Conference on Tobacco Control in 1996. These recommendations provided the framework for the EU Directive in 2001 (37/EC) which, while continuing with the tar reduction approach, also introduced maximum yields for nicotine and carbon monoxide (CO). In addition, the EU Directive 2001/37/EC mandated the publication of tar, nicotine and CO yields on the sides of packs, and introduced the requirement for the industry to disclose their ingredients to the competent authorities in Member States (with onward transmission to the European Commission). EU Directive 2001/37/EC also banned the use of misleading descriptors, such as “mild” and “light”, introduced more prominent health warnings and banned the sale of certain types of oral tobacco, a ban which had been introduced in the EU in 1992. These latter aspects are described in more detail in Chapter 3. This chapter focuses on the tar reduction strategy, ingredients disclosure, and future tobacco product regulation.

Overall, understanding of the field of product regulation has advanced considerably since the late 1990s. In recognition of the growing base of evidence, the EU Directive 2001/37/EC also provided a review clause (Article 11) to take account of emerging scientific knowledge. Suggested areas to review included methodologies for more realistically assessing and regulating toxic exposure and harm, development of standardised testing methods to measure the
yields of constituents in cigarette smoke other than tar, nicotine and CO and the evaluation of tobacco products which may have the potential to reduce harm.

3.1. The tar yield reduction strategy

Reduction in the machine-smoked tar yields of cigarettes was the key strategy for reducing the harmfulness of cigarettes in the last century. As indicated earlier, this strategy was based on the scientific understanding that tar was the principle carcinogenic and toxic component of cigarettes and reducing tar would reduce the likelihood of smokers developing cancers and other diseases. Likewise, setting a maximum yield of CO in the EU Directive 2001/37/EC was thought to limit the risk of developing cardiovascular disease (box 1 shows some selected relevant aspects of the EU tobacco products Directive 2001/37/EC).

Box 1. - EU Directive 2001/37/EC: Selected references to yield reduction strategy

Preamble

(5) Directive 90/239/EEC established maximum limits for the tar yield of cigarettes marketed in the Member States with effect from 31 December 1992. The carcinogenic nature of tar makes it necessary to reduce further the levels of tar in cigarettes.

(7) Several Member States have indicated that, if measures establishing maximum carbon monoxide yields for cigarettes are not adopted at Community level, they will adopt such measures at national level. Differences in rules concerning carbon monoxide are likely to constitute barriers to trade and to impede the smooth operation of the internal market. In addition, cigarettes have been shown to produce amounts of carbon monoxide which are hazardous to human health and capable of contributing to heart disease and other ailments.

(9) There are differences between the laws, regulations and administrative provisions of the Member States on the limitation of the maximum nicotine yield of cigarettes. Such differences are liable to constitute barriers to trade and to impede the smooth operation of the internal market. Member States and scientific authorities have raised specific problems of public health in a field which has already been the subject of prior harmonization measures, which the Commission has examined.

(10) Those obstacles should accordingly be eliminated and to that end the release for free circulation, marketing and manufacture of cigarettes should be made subject to common rules not only concerning tar but also concerning maximum nicotine and carbon monoxide levels.

(14) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are the only internationally recognised standards, it being understood that subsequent research and technological progress to be promoted should make it possible to develop and use more precise and reliable measurement methods for cigarette yields and for developing measurement methods for the other tobacco products.
3.1.1. Problems with tar yield reduction strategy

Tar is defined as the cigarette smoke condensate, or total particulate material minus nicotine and water, collected on the Cambridge filter pad in smoking machines from mainstream smoke (defined as that drawn through the filter by the smoker, as opposed to sidestream smoke which arises from the lit end of the cigarette). The particles in the smoke larger than 1 µm are trapped...

with 99% efficiency, but the gas or vapour phase of the smoke passes mostly through the filter. Therefore, tar yields were measured using these machines by tests involving a set of parameters for the machines. These were introduced by the US Federal Trade Commission and adopted by the International Standards Organisation (ISO; table 1).

Table 1. - Parameters of the standard International Standards Organisation test

<table>
<thead>
<tr>
<th>Puff Volume</th>
<th>35 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puff Interval</td>
<td>1 per minute</td>
</tr>
<tr>
<td>Puff Duration</td>
<td>2 seconds</td>
</tr>
<tr>
<td>Butt Length</td>
<td>23 mm for non-filtered and 3 mm above filter overlap for filter tipped cigarettes (there are slightly different specifications for butt length for the Federal Trade Commission test).</td>
</tr>
</tbody>
</table>

Manufacturers achieved the reduction in machine-measured tar yields using several techniques, such as increasing the ventilation of the filter, increasing the burn rate, decreasing the tobacco density, increasing the porosity of the wrapping paper, changes in tobacco blending and changes in filter efficiency, such as pressure drop alterations. However, the main method used was to dilute the smoke by placing ventilation holes in cigarette filters. This resulted in air also being drawn in through the filter causing a reduction in the machine-registered yields. Both gas and particulate yields were reduced roughly in proportion to the degree of ventilation. On the whole, as tar yields decreased, so did nicotine yields.

Most smoking behaviour is driven by an addiction to nicotine. As most smokers regulate their nicotine intake to maintain a relatively constant intake of nicotine each day, they alter the way they smoke to achieve their preferred nicotine level, a process referred to as compensation. Cigarettes with reduced tar and nicotine yields are smoked more intensively by, for example, taking more and deeper puffs and/or blocking the ventilation holes in cigarettes, to achieve a satisfactory dose of nicotine. The ventilation holes are positioned in the filter where smokers place their fingers, and are, therefore, easy to block. Cigarette-testing machines cannot take account of this relationship between nicotine intake and behaviour as the machine puffing patterns are standardised and with the standard ISO test the ventilation holes were not covered. The ISO machine smoking protocol, therefore, fails to take account of cigarette smoking as predominantly nicotine-seeking behaviour and the cigarette as a delivery system for nicotine.

An illustration of the differences between machine-delivered measurements and smoke intake by smokers is given in figures 1 and 2. Jarvis et al. showed that in a representative sample of smokers in England there was a very wide range in nicotine intake ranging from just above 0 to 50 mg nicotine per day for cigarettes having the same machine measured nicotine yields (fig. 1). Figure 2 shows that the actual nicotine intakes differed greatly from the predicted nicotine intakes and were broadly similar across the range of machine-delivered nicotine yields. These graphs indicate that the machine tests cannot be used to measure what smokers are actually taking in from their cigarettes.
Fig. 1. - Scatterplot relating cigarette nicotine yields and saliva cotinine concentrations in 2031 smokers participating in the 1998 Health Survey for England

\[ \text{Cotinine} = 173.5 + 138.7 \times (\text{nicotine yield}) \; \text{;} \; r=0.19, \; r^2=0.034. \text{Adapted from Jarvis et al.}^{17} \]

Fig. 2. - Predicted and actual nicotine intakes per cigarette smoked by nominal nicotine yield of usual brand

\[ \text{Health Survey for England 1998} \]

- Actual Intake by smoker
- Predicted Delivery to smoking machine

Adapted from Jarvis et al.\textsuperscript{17}
The other main problem with the reduction in tar yield approach is around the concept of reducing “tar”. More than 2,000 chemical constituents exist in tobacco and about twice that number when tobacco is burned during smoking. “Tar” has markedly different compositions across different products and across different countries. Hence, it is misleading to view “tar” as a consistent homogeneous toxic substance.

3.1.2. Public health impact of reductions in yields

Recent reviews have concluded that there is no convincing evidence of any benefit to public health from the strategy of reducing machine-based tar yields. Reductions in machine-smoked tar yields can be achieved relatively easily by changing the design of the cigarette, and together with compensatory changes in smoking behaviour, these do not result in differences in exposure to the smoker. Although in some countries in Europe lung cancer rates have decreased over the last few decades, there are many competing explanations for the decline, foremost among them being the decline in prevalence of smoking, but possibly also the introduction of other changes in the manufacture of cigarettes. Indeed, despite reductions in machine-based tar yields in the USA, no corresponding decrease has been found in lung cancer rates there.

3.2. Regulation of nicotine

A central issue in tobacco product regulation is what approach should be adopted towards nicotine. Nicotine is clearly the reason why most smokers smoke but it does not cause most of the harm.

Some experts had envisaged that the most effective approach to the regulation of nicotine would be to eliminate nicotine addiction by progressively reducing the levels of nicotine in tobacco products to zero, or a level approaching zero.

Most scientists and tobacco-control experts now reject this approach. This is because of the basic premise that nicotine drives smoker behaviour, so if nicotine yields are reduced then smokers are likely to compensate by inhaling more, resulting in no change or an increased toxicity (see earlier and Chapter 1). Among those experts are some of the previous most ardent promoters of the elimination approach. For example, recently, Henningfield et al. came to the conclusion that “a more politically feasible option is that regulated products would retain the capacity to sustain addiction in existing tobacco users and hence some level of addiction risk”.

However, regulating nicotine is important in being able to shape the market for nicotine products. Hence, the nicotine limit implemented through the EU Directive 2001/37/EC was an important harmonisation measure, which has, in principle, brought the nicotine delivery of cigarettes under regulatory control. The WHO TobReg acknowledges that a broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in ways that minimise the risks. The committee calls for further study on how best to do this since “it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine.”
4. A NEW REGULATORY FRAMEWORK FOR REGULATING NICOTINE AND TOBACCO PRODUCTS

To date, as described earlier, regulation of the product has focused mainly on one aspect of the cigarette: emissions, in the form of tar, nicotine and CO, and their measurement by machine-based tests.

The complexity of cigarettes requires that regulation to reduce their harmfulness should instead focus on a number of dimensions and be grounded in a proper understanding of smokers’ behaviour. Therefore, a comprehensive assessment of the product needs to be made across a wide spectrum of parameters. Table 2 outlines the parameters that would need to be assessed as part of a comprehensive regulatory framework for tobacco products. These dimensions are interrelated. For example, the physical design characteristics interact with the chemical constitution of the product and influence exposure.

Table 2. - A comprehensive regulatory framework for nicotine and tobacco products

| • PRODUCT CHARACTERISTICS AND EMISSIONS |
| • EXPOSURE |
| • INJURY |
| • DISEASE RISK |
| • CLAIMS |
| • RESEARCH, EVALUATION AND MONITORING |

Assessment of some of these factors is largely in its infancy. This section only briefly describes some of the key issues involved and the reader should refer to the recent Institute of Medicine report\(^ \text{2} \) and the WHO TobReg guidelines\(^ \text{6} \) for more details.

As discussed at the outset, this regulatory framework should apply to all types of nicotine delivery systems, including new and modified tobacco products\(^ \text{6} \) and nicotine replacement therapies, which are currently regulated separately by medicines regulators.

**Recommendation:** A new comprehensive regulatory framework for all tobacco and nicotine products needs to be implemented.

4.1. Product characteristics and emissions

There are many aspects of the design and make up of cigarettes that affect exposure to tobacco constituents and the harm caused by smoking.

Full disclosure of the physical, chemical and design characteristics of tobacco products is required (table 3).

Too little is currently known about each aspect to enable regulators to devise appropriate strategies. Strengthening the information requirements from the tobacco industry to cover the above issues and increasing compliance are, therefore, important first steps in order to be able to shape effective tobacco regulation in the future\(^ \text{22} \).
Recommendation: Comprehensive disclosure of the physical, chemical and design characteristics of all tobacco products should be required and made public. This should include, inter alia, the type of tobacco used, the way the tobacco is processed, ingredients added, product engineering, physical and chemical characteristics of the emissions of all tobacco products, the availability of nicotine and other psychoactive constituents, the mode of use and the behaviour of the user.

So far, the EU has focused on requiring manufacturers to disclose additives ("ingredients"). This requirement and the industry response are described in the next section. However, as can be seen from table 3, additives are only one very small aspect of tobacco product engineering.

### 4.1.1. Ingredients

The definition of ingredients used in this report is that given by the EU Directive 2001/37/EC. Accordingly "ingredient" means:

> "any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives."\(^a\)

The term "ingredient" encompasses the commonly used term "additive" and the EU Directive 2001/37/EC (and this chapter) uses these two terms interchangeably (box 2). These two terms have different meanings in Canadian tobacco-control legislation. The term "additive" has a slightly less comprehensive definition than the EU definition of "ingredients" (box 3) as it does not consider paper and filter materials to be additives. The Canadian legislation defines "ingredients" as the materials of tobacco products which are not additives. There is no corresponding term for these in the EU legislation.

---

\(^a\) The EU Directive 2001/37/EC is not entirely consistent in its use of the term "ingredients", in that it applies the term also to tar, nicotine and carbon monoxide (Article 6, point 3) and uses both this term and the term "additives" inconsistently in the preamble (box 2).
Box 2. - Content of EU Directive 2001/37/EC: references to ingredients or additives

Preamble

(22) The situation varies in the different Member States regarding the ingredients and additives used in the manufacture of tobacco products. A number of Member States have neither existing legislation nor voluntary agreements in place on those substances. Several Member States in which such legislation or voluntary agreements exist receive no information from tobacco manufacturers on the quantities of such ingredients and additives present in particular tobacco products on a brand name by brand name basis. An approximation of the measures applicable in this field should be introduced, resulting in greater transparency.

(32) As regards the other ingredients, including additives, the drawing up of a common list ought to be considered, with a view to subsequent harmonisation.

Article 6

Further product information:

1. Member States shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. The information referred to in the first subparagraph shall be provided on a yearly basis and for the first time by 31 December 2002 at the latest.

2. Member States shall ensure the dissemination of the information provided in accordance with this article by any appropriate means, with a view to informing consumers. Due account shall nevertheless be taken of protection of any information on specific product formulae which constitutes a trade secret.

3. Member States shall ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.

4. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which shall take account thereof when drawing up the report referred to in Article 11.

Article 11

Report [pay special heed to... (inter alia):]

- evaluation of the addictive effects of those ingredients which encourage addiction
Few ingredients were used in cigarettes before 1970. In 1979, the UK was among the first countries in Europe to publish a list of approved tobacco additives (around 350 in total). This followed the setting up of a voluntary agreement between tobacco manufacturers and importers and UK Health Ministers not to introduce new products containing additives, other than those found acceptable to the Independent Scientific Committee of Smoking and Health. The Committee at that time recognised that some additives could improve the acceptability of lower tar cigarettes or be used for technological reasons in the manufacture of cigarettes, for example, to prevent the fall of ash, to control the rate of burning or inhibit the formulation of mould. Today, additives may constitute >15% of weight of cigarettes in the EU. Potentially, hundreds of toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use.

**Article 12**

**Common list of ingredients**

In the framework of the first report referred to in Article 11, at the latest by 31 December 2004, and with a view to the proper functioning of the internal market, the Commission is invited to submit, on the basis of the information provided under Article 6, a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness.

**Article 13**

**Import, sale and consumption of tobacco products**

3. In particular, Member States may provide for the prohibition, pending the establishment of the common list of ingredients referred to in Article 12, of the use of ingredients which have the effect of increasing the addictive properties of tobacco products.

**Box 3. - Terminology of ingredients and additives in tobacco products in Canadian legislation**

**Additive means**

“any substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is introduced by a manufacturer into the tobacco, paper or filter of a cigarette or into cigarette tobacco during the processing, manufacturing or packing of the cigarette or cigarette tobacco.”

**In Canada, contrary to the EU, ingredient means**

a) “tobacco, water or reconstituted sheet and
b) any substance, chemical or compound, other than additives, in the paper or filter of a cigarette.”

Modified from the Canadian Tobacco Sales Act. Few ingredients were used in cigarettes before 1970. In 1979, the UK was among the first countries in Europe to publish a list of approved tobacco additives (around 350 in total). This followed the setting up of a voluntary agreement between tobacco manufacturers and importers and UK Health Ministers not to introduce new products containing additives, other than those found acceptable to the Independent Scientific Committee of Smoking and Health. The Committee at that time recognised that some additives could improve the acceptability of lower tar cigarettes or be used for technological reasons in the manufacture of cigarettes, for example, to prevent the fall of ash, to control the rate of burning or inhibit the formulation of mould. Today, additives may constitute >15% of weight of cigarettes in the EU. Potentially, hundreds
of additives are commonly used. Although most of them are used in very small amounts (<0.01% of total weight), a small group of additives are used at much higher levels, such as sugars, humectants, ammonia compounds, cocoa, licorice and menthol.

In 1997 the Commission Services wrote to all Member States regarding their policy on additives in cigarettes. The analysis of the replies indicated that there was a wide variety of rules concerning additives between the Member States. Common to all these rules was that the issuing authorities were only concerned with the toxic effects of the ingredients in their natural state, i.e. in unburned form (as generally practiced in the regulation of additives to foodstuff). However, none of the rules consider the effects of these additives when used as intended i.e. their uptake by the smoker in the burnt form, when these substances are likely to be considerably more toxic than their unburned form.

To the credit of the European Commission and following the recommendation of the cancer experts committee, EU Directive 2001/37/EC introduced regulations to take into account the effect of ingredients in their burnt form (Article 6, point 1).

EU Directive 2001/37/EC further improved upon previous practice. Up until then, regulations had concentrated only on the “direct” toxic effects of ingredients, thus ignoring the indirect effects of ingredients on the health of smokers, such as enhancement of addictiveness, which might result in increased consumption and harm. EU Directive 2001/37/EC explicitly requires the indirect effects to be now taken into consideration (Article 6, point 1).

The remainder of this section focuses on the major requirements of EU Directive 2001/37/EC regarding ingredients: first, the requirement for disclosing amount and function of ingredients, secondly, their toxic effects and, thirdly, the call for establishing of a common “positive” list of ingredients. It concludes by making other recommendations for further development.

4.1.1.1. Disclosure of amount and function

A fundamental issue in guiding requests for information is to ensure that the definition of ingredients is sufficiently broad. In this respect, the EU Directive 2001/37/EC reflected the state of regulatory awareness at that time, essentially limiting ingredients to substances which were added during the manufacturing process alone. Since then, it has emerged that some substances may enter the product during earlier phases, such as through agricultural practices. These substances are excluded from the definition, and, therefore, from regulation despite the fact that they are present in the final product, and ingested by the smoker. One example of an ingredient of this kind is ammonia, a substance known to alter the form of nicotine and hypothesised to increase the addictiveness of nicotine. Ammonia is present in the tobacco leaf itself and ammonium salt may be added to the growing process.

A more comprehensive definition of ingredients, such as that developed by the WHO RegTob (formerly SACTOB), will ensure that all substances, potentially harmful to human health, can be captured by the regulatory process. According to the RegTob definitions: “ingredients include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from packaging into the product.”
**Recommendation:** The current EU Directive 2001/37/EC should be improved by adopting the WHO TobReg definition for ingredients.

Article 6 of the EU Directive 2001/37/EC also calls on Member States to require a list of all ingredients and the quantities used from tobacco manufacturers and importers (box 2). This had to be provided by brand name and type, and explain why each additive was used. Member States were to ensure that this information be disseminated to inform consumers. But the requirement to do so was qualified by reference to trade secrecy.

To date, tobacco companies have not complied with this part of the EU Directive 2001/37/EC, arguing that a comprehensive list of ingredients is too detailed for the consumer and that authorities do not give enough guarantees that the confidential information on quantities will not be leaked to outsiders.

**Recommendation:** The tobacco industry is required to fully disclose additives used in their products according to the letter and spirit of the EU Directive 2001/37/EC. In view of the high risk potential of tobacco products, such detailed information should take precedent over trade secrecy.

4.1.1.2. Disclosure of toxic and addictive effects

Article 6 of the EU Directive 2001/37/EC also stipulates that the list of additives should be “accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate” with particular reference to their effects on health and addictive effects (box 2).

One major shortcoming of the regulation is that the industry is asked only to provide available scientific data on the toxicology or addictiveness of ingredients. Thus, the regulations give no precision around which information should be transmitted, which methods for measurement should be used, and whether data should be present for each ingredient or all ingredients taking into account their synergistic effects.

How toxicity is defined for regulatory purposes remains highly controversial. Tobacco companies submit that the toxicity of ingredients should be evaluated relative to that of the overall toxicity of tobacco products, rather than on the basis of their own absolute toxicity. Under this premise, the industry compares the toxicity of tobacco products and tobacco smoke in the presence or absence of a mixture of ingredients and claims that any ingredient which does not cause excess toxicity could be authorised for use. This means that authorised ingredients might be as toxic and carcinogenic as the tobacco smoke constituents themselves. Such an approach is clearly not acceptable. Tobacco products, albeit extremely toxic and addictive, are legal because they could not be banned in view of the hundreds of millions of tobacco addicts. However, this is entirely different for additives. According to good regulatory practice additives should not be harmful. There is no good reason why this practice should not apply to tobacco additives in their unburnt and burnt form. In essence, the toxicity of tobacco and tobacco smoke cannot be the standard for evaluating the toxicity of ingredients as proposed by the tobacco industry. The additives have to be tested for their own toxicity, as is required for additives for any other consumer product.
The information on addictiveness is even more likely to be unsatisfactory as the official position of the tobacco industry has always been that they never add ingredients which enhance addictiveness.

A further shortcoming in this context is a lack of regulatory capacity to cope with the volume of information which will be received. It is doubtful whether Member States have the competence and capacity to examine, check and control the data provided by the industry, at present and, indeed, whether there are enough independent laboratories across the EU to examine the industry data (see section Regulatory capacity in Europe).

In conclusion, the information provided by the tobacco companies, thus far, is insufficient to form the basis for further regulations for ingredients and, in particular, the drawing up of a common list of ingredients, another requirement of the EU Directive 2001/37/EC as described in the next section.

**Recommendation:** Member States and the European Community should agree a harmonised system for receiving the required information on ingredients in, and emissions from, tobacco. This system should specify the exact form and content of the information to be transmitted, which methods for measurement should be used and that the data should also take into account synergistic effects of the ingredients. The information provided should allow comparability between different tobacco companies. A harmonised system should also be established for Member States to analyse, verify and then report this information to the European Commission.

### 4.1.1.3. A common list of ingredients

Article 12 of the EU Directive 2001/37/EC calls for the Commission to submit, on the basis of information provided in Article 6 of the EU Directive 2001/37/EC, “a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness” (Box 2). This proposal was to be made at the latest by 31 December 2004.

The requirement for a common list came about because of concerns that an additive approved in one EU Member State had to be permitted in all states and there was a concern that this would lead to tobacco companies seeking approval in the weakest regulatory regime.

It is not yet clear which additives should be on the common list. As discussed in the previous section there are no clear criteria for measuring toxicity and addictiveness. In particular, methodologies for assessing toxicity and addictiveness of ingredients have to be established and validated for sensitivity, specificity, and comparability across different laboratories. This is a demanding task requiring skills and expertise not currently widely available among tobacco-control scientists, researchers and regulators. Methodologies for assessing addictiveness are not well developed and not applicable to routine, large-scale monitoring and it may take years for them to be agreed.

However, test procedures for assessing carcinogenicity, likely to be the most important toxic effect of ingredients, are well established and can readily be applied in the first instance to test ingredients. Methodologies for assessing addictiveness and other toxic properties should be applied as they become available.
One starting point for the development of a robust regulatory framework for ingredients would be the tests used by cosmetics or medicines regulators for pharmaceutical products.

**Recommendation:** A common list of ingredients cannot be produced until scientifically agreed criteria have been drawn up to assess the toxicity and addictiveness of ingredients and their public health impact (see below).

### 4.1.1.4. A public health test for additives

As indicated above, regulations previously ignored the *indirect* effects of additives on the health of smokers. Ingredients may increase harm in more ways than by enhancing direct toxicity and addictiveness. They may increase the uptake of toxic constituents of tobacco smoke. This is the case, for example, with menthol, which causes respiratory depression resulting in greater exposure to toxicants in tobacco smoke\(^{33, 34}\). Even more importantly, additives may enhance overall consumption and subsequent harm by making the product more palatable and attractive to the consumer\(^{35}\).

As the toxicity of most additives is greatly outweighed by the toxins present in tobacco smoke, then what is important is if the ingredient acts in such a way that leads to increased smoking. Such a mechanism of action would have a far greater impact on public health than the direct toxicity of the ingredients.

However, it is important to note that additives are sparingly used in some countries such as Canada and certain types of cigarettes (e.g. the brand named “Natural American Spirit” manufactured by Santa Fe Natural Tobacco Company, Inc., Santa Fe, NM, USA) claim to be free of additives. Thus, the majority of ingredients do not seem to be necessary for the manufacture of cigarettes and their acceptance by consumers.

The criteria for assessing existing and new additives should, therefore, be extended to include a test of public health or public interest (with the burden of proof resting on the industry) or be withdrawn from use. Exemptions should only be made for ingredients which are necessary for the manufacture and storage of tobacco products providing they are safe.

**Recommendation:** Any future regulation of ingredients should be based on the principles that the substance is not toxic, does not enhance the addictive properties of tobacco products and does not make the product more attractive. Further research and analysis is needed to create scientifically sound criteria for any approval or prohibition of ingredients.

### 4.1.2. Ignition propensity

One characteristic of cigarettes that should be regulated is ignition propensity\(^{22}\). Smoking is a leading cause of residential and total fire death\(^{36}\). The number of smoking-related fire deaths in Canada and the USA amounts to 25% and 30%, respectively, of total fire deaths. Assuming a proportion of 20% of smoking-related fire deaths in EU Member States, fires caused by smoking claim more than 1,000 victims annually in the EU. Many of the smoking-related fires could be prevented through the introduction of a fire safety standard for cigarettes.

Internal documents of the tobacco industry reveal that low ignition propensity cigarettes could have been produced as early as 1985\(^{37}\). The documents also indicate that the production of such
cigarettes would not be significantly more costly or affect their taste. It took two decades until “fire safe” cigarettes reached the USA market. New York has now enacted a law requiring that only self-extinguishing cigarettes can be sold. Other USA states such as Massachusetts, Minnesota, New Jersey and Rhode Island are considering taking similar steps. Canada will be the first country to follow suit by permitting only self-extinguishing cigarettes on the market in 2005. Testing methodologies for cigarette fire safety have been developed in the USA and Canada that can be readily adopted elsewhere.

**Recommendation:** In view of the fact that it is technologically and economically feasible for cigarettes to meet fire safety standards, tobacco manufacturers should be required to produce and market only “fire safe” (or “reduced ignition propensity”) cigarettes in the EU.

### 4.1.3. Emissions

The term emissions covers all the substances produced when the tobacco product is used. As described earlier, to date, the regulation of emissions has been limited to measuring tar, and more recently nicotine and CO, relying on the inadequate machine tests.

Two main approaches have been suggested to overcome the current limitations. The first approach involves changing the operating parameters of the machine to make it more closely mimic smoking behaviour. The second uses the ratio of the standard ISO tar and nicotine yields as an indicator of potential harm. These approaches are described briefly below.

#### 4.1.3.1. Intense machine smoking regimens

Some countries have introduced more intense standards for machine cigarette testing. The first to do this was British Columbia, in 1998 through the Tobacco Testing and Disclosure Regulation 26. This Regulation, inter alia, required Canadian tobacco manufacturers to disclose the constituents of tobacco and the levels of potentially toxic chemicals in tobacco smoke (both mainstream and sidestream), for a number of smoke constituent chemicals, using both the standard ISO test as well as a modified ISO or intense puffing test (table 4). The Modified ISO test was designed to assess the maximum yields of a cigarette that could be made available to a smoker so the parameters of the test were set to try to maximise the amount of smoke that could be inhaled.

<table>
<thead>
<tr>
<th></th>
<th>STANDARD ISO</th>
<th>MODIFIED ISO (1)¹</th>
<th>MODIFIED ISO (2) ¶</th>
<th>MASSACHUSETTS MODIFICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puff volume</td>
<td>35 mL</td>
<td>56 mL</td>
<td>55 mL</td>
<td>45 mL</td>
</tr>
<tr>
<td>Puff interval</td>
<td>60 seconds</td>
<td>20 seconds</td>
<td>30 seconds</td>
<td>30 mL</td>
</tr>
<tr>
<td>Puff duration</td>
<td>2 seconds</td>
<td>2 seconds</td>
<td>2 seconds</td>
<td>2 seconds</td>
</tr>
<tr>
<td>Ventilation holes</td>
<td>Not blocked</td>
<td>Fully blocked</td>
<td>Fully blocked</td>
<td>50% blocked</td>
</tr>
</tbody>
</table>

¹: Used for the 1998 and 1999 reporting years; ¶: used for the 2000 and beyond reporting years. Modified from British Columbia Tobacco Testing and Disclosure Regulations.38.
Health Canada subsequently adopted the Modified ISO (2) test method in their Federal Tobacco Reporting Regulation and required both standard and modified measures to be made available to consumers on packs in the form of a range.

The Massachusetts Department of Health proposed reporting requirements for smoke constituents using a further modification of the ISO test which reduced the parameters of the Canadian modifications to make them more realistic (table 4), but this has not yet become legislation.

4.1.3.2. Tar/nicotine ratios

As early as 1976 it was proposed that the yield of tar should be determined relative to that of nicotine and that cigarette smoking could be made less hazardous by reducing tar and other toxins relative to nicotine. This approach is based on the evidence that smokers tend to regulate their nicotine intake to obtain a “satisfactory” dose level which is constant over time and that they will compensate for reductions in nicotine yield by inhaling more from their cigarettes to maintain a relatively consistent dose of nicotine. So if the nicotine level is maintained whilst reducing the tar yields then smokers would not need to compensate and so their inhalation of tar would be reduced. This strategy is referred to as regulating the tar/nicotine ratio of emissions. A ratio of 10 would mean that for each unit of nicotine, 10 units of tar would be delivered, whereas a ratio of 20 would mean 20 units of tar being delivered for each unit of nicotine. Hence, a lower tar/nicotine ratio is preferred because this would mean less tar per unit of nicotine inhaled. A limit of 10 could be set for the ratio, together with individual tar and nicotine yield limits (in order to avoid possible combinations of high tar and high nicotine yields).

However, this approach has some pitfalls which were not known at the time. The tar/nicotine ratio can also vary depending on how the cigarette is smoked. In 1986 Rickert et al. indicated that a tar/nicotine ratio of 6.1 on a smoking machine could become 9.7 in a smoker trying to increase the amount of nicotine in an ultra-light cigarette. Instead of using the standard ISO tests to construct the ratio, it may be preferable to use the modified ISO tests so as to better mimic smoking behaviour.

Recently, the Laboratory of the Government Chemist in England tested 12 cigarette brands available on the UK market in 1999 using standard, British Columbia and Massachusetts modified testing (Modified ISO (1) on table 4) regimes and compared tar and nicotine yields and tar/nicotine ratios with each test. Table 5 details the findings of this study.

The misleading nature of the lower yielding brands (table 5, column 1) is demonstrated when the standard ISO tar/nicotine ratios are considered (table 5, column 3). There is little difference between the higher and lower tar yield brands when the standard ISO tar/nicotine ratios are considered.

The tar/nicotine ratios of lower yielding brands appear to have slightly lower tar to nicotine ratios than higher yielding brands when using the standard ISO tests (table 5, column 3). However, when comparing the tar/nicotine ratios constructed using the standard ISO tests, compared with the British Columbia (BC) modified test, the very intense human smoking regimens, (table 5, column 10) the tar/nicotine ratios from lower yielding cigarettes are considerably greater, and for some low yield brands indicate greater tar per dose of nicotine being delivered than with the higher tar yield brands.
The differences between the tar/nicotine ratios for the “more realistic” Massachusetts test and the standard ISO test are more closely approximated (table 5, column 11). It is worth noting that in this sample of cigarette brands the ratios vary considerably less (1.4 fold) than the actual tar yields (12 fold), so the ratio measurement may have more validity.

Introducing a ratio limit could take many more brands off the market within the EU than are affected by the current EU Directive 2001/37/EC. If a tar/nicotine ratio of 10 was introduced into the EU, column 3 (table 5) indicates that only two of the brands tested in the UK study would comply. If the same limit was applied to the ratio of yields determined by the BC/ISO T/N# columns, only one of the brands tested in the UK study would comply.

### Table 5. - Tar (T) and tar/nicotine (T/N) ratios of a selection of UK brands using the standard International Society Organisation (ISO) machine tests, and the more intensive British Columbia (BC) and Massachusetts (Mass) smoking regimes

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Silk Cut Ultra KS</td>
<td>1.01</td>
<td>0.11</td>
<td>9.18</td>
<td>31.18</td>
<td>1.95</td>
<td>15.96</td>
<td>9.11</td>
<td>0.84</td>
<td>10.89</td>
<td>1.74</td>
<td>1.19</td>
</tr>
<tr>
<td>Mayfair Ultra KS</td>
<td>1.19</td>
<td>0.12</td>
<td>9.92</td>
<td>30.34</td>
<td>1.8</td>
<td>16.87</td>
<td>8.97</td>
<td>0.79</td>
<td>11.37</td>
<td>1.7</td>
<td>1.15</td>
</tr>
<tr>
<td>Silk Cut Ex Mild KS</td>
<td>2.91</td>
<td>0.29</td>
<td>10.03</td>
<td>32.73</td>
<td>2.04</td>
<td>16.1</td>
<td>12.86</td>
<td>1.14</td>
<td>11.31</td>
<td>1.6</td>
<td>1.13</td>
</tr>
<tr>
<td>Superkings Ultra</td>
<td>3.36</td>
<td>0.31</td>
<td>10.84</td>
<td>28.77</td>
<td>1.7</td>
<td>16.97</td>
<td>11.18</td>
<td>0.94</td>
<td>11.91</td>
<td>1.57</td>
<td>1.1</td>
</tr>
<tr>
<td>Red Band Lights S/K</td>
<td>5.73</td>
<td>0.53</td>
<td>10.87</td>
<td>40.16</td>
<td>2.56</td>
<td>15.66</td>
<td>18.3</td>
<td>1.46</td>
<td>12.57</td>
<td>1.44</td>
<td>1.16</td>
</tr>
<tr>
<td>Embassy Ex Mild KS</td>
<td>7.8</td>
<td>0.7</td>
<td>11.14</td>
<td>33.51</td>
<td>2.3</td>
<td>14.57</td>
<td>19.34</td>
<td>1.63</td>
<td>11.86</td>
<td>1.31</td>
<td>1.06</td>
</tr>
<tr>
<td>Balmoral Lights KS</td>
<td>8.09</td>
<td>0.64</td>
<td>12.64</td>
<td>36.9</td>
<td>2.35</td>
<td>15.69</td>
<td>19.78</td>
<td>1.51</td>
<td>13.08</td>
<td>1.24</td>
<td>1.03</td>
</tr>
<tr>
<td>Superkings Lights</td>
<td>8.29</td>
<td>0.82</td>
<td>10.11</td>
<td>37.03</td>
<td>2.9</td>
<td>12.8</td>
<td>20.57</td>
<td>1.97</td>
<td>10.42</td>
<td>1.27</td>
<td>1.03</td>
</tr>
<tr>
<td>Benson &amp; Hedges KS</td>
<td>10.66</td>
<td>0.85</td>
<td>12.54</td>
<td>39.91</td>
<td>2.64</td>
<td>15.13</td>
<td>24.33</td>
<td>1.89</td>
<td>12.89</td>
<td>1.21</td>
<td>1.03</td>
</tr>
<tr>
<td>Rothmans KS</td>
<td>11.02</td>
<td>0.95</td>
<td>11.6</td>
<td>41.48</td>
<td>3.03</td>
<td>13.67</td>
<td>24.7</td>
<td>2.19</td>
<td>11.26</td>
<td>1.18</td>
<td>0.97</td>
</tr>
<tr>
<td>Marlboro KS</td>
<td>12.01</td>
<td>0.86</td>
<td>13.97</td>
<td>45.31</td>
<td>2.71</td>
<td>16.73</td>
<td>27.86</td>
<td>1.95</td>
<td>14.26</td>
<td>1.2</td>
<td>1.02</td>
</tr>
<tr>
<td>Raffles 100's</td>
<td>12.36</td>
<td>1.1</td>
<td>11.24</td>
<td>42.45</td>
<td>3.52</td>
<td>12.08</td>
<td>26.84</td>
<td>2.47</td>
<td>10.89</td>
<td>1.08</td>
<td>0.97</td>
</tr>
</tbody>
</table>

# These columns show the relationship between the tar/nicotine ratios from the two modified testing regimes and the tar/nicotine ratios from the standard ISO tests. Modified from Laboratory of the Government Chemist42 .

The differences between the tar/nicotine ratios for the “more realistic” Massachusetts test and the standard ISO test are more closely approximated (table 5, column 11).

It is worth noting that in this sample of cigarette brands the ratios vary considerably less (1.4 fold) than the actual tar yields (12 fold), so the ratio measurement may have more validity.
Modified ISO tar/nicotine protocol (table 5, column 6) none of the brands tested would comply.

Therefore, both the intense smoking tests and the tar/nicotine ratio offer improvements on the standard ISO tests. As these approaches do not require the development of new technologies they could be implemented quickly, thereby putting an end to the present highly unsatisfactory situation. At present, it is unclear which approach (BC Modified, Massachusetts modified or tar/nicotine ratio using standard, BC or Massachusetts tests) is the best protocol to follow or whether a combination of the different approaches would be the best way forward. This is an urgent issue which needs to be clarified by European experts, drawing on the experience of those in Canada and Massachusetts who have used the modified ISO tests, and in coordination with other international bodies concerned with tobacco product regulation, such as WHO TobReg.

The protocols described above continue to rely on “tar” as the key indicator of toxicity. As explained earlier in this chapter, the concept of “tar” needs to be supplemented with a more sophisticated understanding of the different constituents of tobacco and/or smoke as described in the following section.

4.1.3.3. Disclosure and reduction of individual smoke constituents

On this basis, experts now prefer to examine and regulate the disclosure and reduction of individual smoke constituents. Disclosure requirements should, therefore, also include details of a variety of smoke constituents. This is an approach followed by Health Canada. The following major types of constituents should be disclosed:

- Polycyclic aromatic hydrocarbons (e.g. benzo[a]pyrene, 5-methylchrysene)
- N-Nitrosamines (e.g. 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosonornicotine (NNN))
- Aromatic amines (e.g. 4-aminobiphenyl, 2-naphthylamine)
- Organic solvents (e.g. benzene, toluene, styrene)
- Volatile organic compounds (e.g. 1,3-butadiene, isoprene)
- Aldehydes (e.g. acetaldehyde, formaldehyde)
- Gaseous constituents (e.g. hydrogen cyanide, nitrogen oxide)
- Inorganic compounds (e.g. arsenic, cadmium, polonium-210)

In addition to disclosure, upper limits should be set for single constituents or a “representative” set of constituents drawn from the list above. These limits should then be progressively lowered to minimise harm and addictiveness of the tobacco product.

Exemplary candidates for early mandatory reduction are the tobacco specific N-nitrosamines (TSNAs). TSNAs are found in the particulate phase of tobacco smoke but also in non-combustible tobacco. TSNAs are not present in freshly harvested tobacco but are formed during tobacco curing. The TNSA yield is dependent on the amounts of nitric oxide in the heated air and the amounts of nitrates and nicotine in the tobacco. The main TSNAs thought to be carcinogenic are NNK and NNN. These compounds can largely be removed from tobacco, i.e. they can be prevented from being generated by taking appropriate precautionary measures during manufacture. Combustible and non-combustible tobacco products
distinguished by very low levels of TSNAs are already on the market in the USA and Europe, respectively.

It has been recommended that a mandatory reduction of TSNAs should be an immediate priority for the EU, provided that in doing so the overall toxicity of cigarette smoke is not increased. A precedent for this already exists as EU legislation has been passed to reduce nitrite/nitrate levels in some meat products.

Since the public health impact of the TSNAs removal cannot be predicted with certainty at the present time, the move should not be accompanied by any communications by the tobacco industry to the public implying a health benefit (see below).

**Recommendation:** Harmful constituents of tobacco and tobacco smoke should be reduced and ultimately removed where feasible. As a first step, the immediate reduction of TSNAs in tobacco products, without increasing the overall harm caused by these products, should be made mandatory.

### 4.2. Exposure

The WHO TobReg defined the difference between emissions and exposure as:

> "'Emissions' are substances that are produced when the product is used and this is distinguished from 'exposure', a term that in this context refers to the fraction of emissions that is actually absorbed by the user."7

Increasing the understanding of the actual exposure of smokers to toxins and nicotine and the impact of this on their health is critically important. It will also be necessary to monitor smokers’ exposure to nicotine and cigarette smoke toxins over time. The failure of the low tar strategy hinged on the fact that only emissions to cigarette-testing machines were measured over time, rather than the actual exposure of smokers to various smoke constituents. Measuring exposure is an indicator of potential harm and disease, and can also indicate how smokers and the industry are responding to product regulation. This can help assess the effectiveness of product regulation strategies and enable changes to the strategies to be made relatively quickly if unforeseen consequences are being observed.

There is an approach for assessing exposure which is independent of machine measurements and based on the actual behaviour of the smoker. This approach involves the measurement of tobacco smoke constituents trapped in the filter during actual smoking. In principle, such measurements reflect closely the behaviour of the smokers. A first attempt at this has been made using solanesol as an indicator, a naturally occurring component of tobacco that is deposited during smoking in the filter butt. The amount of solanesol trapped on a filter was found to be related to the mainstream deliveries of tar and nicotine under a variety of ISO standard and modified smoking conditions. Currently it has only been tested with cigarettes containing cellulose acetate filters.

Uptake of toxic tobacco constituents by smokers can be determined directly by measuring their levels, for example in body fluids. At present, the number of constituents which can serve as “biomarkers” is greatly limited. Furthermore, many of the salient methodologies are not yet applicable to large scale, routine measurements. However, saliva cotinine (a non-
invasive indicator of nicotine exposure) testing over time is feasible. The saliva cotinine test is easy to administer and it enables a quantitative measure of nicotine intake to be monitored in smokers over time.

4.3 Injury and disease risk

There are three main major health outcomes of tobacco consumption which need to be monitored: cancer, cardiovascular disease and lung disease. Ideally, smokers' risks of suffering from one of these diseases should be determined by epidemiological studies. However, because of the length of time for such diseases to manifest themselves, it is not feasible to do this for regulatory practice and one has to resort to surrogate measurements.

For assessing carcinogenicity, well established bioassays are available, such as in vitro genotoxicity/mutagenicity tests or in vivo tests for the development of tumours. Such tests should be routinely used to assess the products currently on the market and new ones before entry.

Bioassays are not yet available for the pathogenesis of cardiovascular disease and lung disease. Although a number of bio-indicators for these diseases are known, such as inflammation, oxidative stress and malfunction of endothelial cells, tests for these indicators are still in an exploratory stage. They have to be validated and standardised. At present, this is one of the greatest challenges in developing a scientific base for evaluating and regulating potential harm reduction products, i.e. to distinguish relative injuries caused by different exposures to toxic tobacco constituents. The Institute of Medicine has estimated that the development of these tests will take a number of years before they can be applied to regulatory practice.

It is not the purpose of this report to review the status of the bioassays for the various smoking-related diseases, but this should be an urgent task within the regulatory framework.

**Recommendation:** Member States and the European Commission need to begin to assess injury risk from tobacco products. A stepwise procedure should be used, starting with established tests e.g. for cytotoxicity and genotoxicity, and then continuing with testing for other adverse effects, including enhancement of addiction.

4.4. Claims

The EU has already banned all use of misleading descriptors, but ISO yields still remain on packs (see Article 5 of the EU Directive 2001/37/EC and Box 1). Based on the evidence provided above, these yields provide misleading information to smokers and should be removed from cigarette packs as soon as possible. This recommendation was a conclusion of the recent EU conference in Limerick, Ireland and has also been made by WHO TobReg. The remaining space on packs should be reserved for consumer information mandated by the European Community.

Communication related to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated to prevent consumers being misled into believing products are significantly less harmful (as occurred with lower yielding cigarettes) and, therefore, continuing to use the products rather than attempt to quit.
**CHAPTER 5**

**Recommendation:** The requirement for tobacco manufacturers and importers to print tar, nicotine and CO yields on packs should be rescinded, and the Commission should mandate the remaining space on packs to be reserved for consumer information provided by Member States and the European Commission.

**Recommendation:** Communication relating to health aspects of different tobacco and nicotine products and any changes in their characteristics should be strictly regulated. The mandatory phasing out of toxic constituents recommended in this chapter should not be accompanied by any health claims.

4.5. Research, evaluation and monitoring

An essential element of the regulatory framework will be the ability to monitor for unintended consequences of modified products as well as to verify industry claims of reduced toxicity in their products. Therefore, changes will need to be monitored and evaluated within a comprehensive system of surveillance which will assess the impact of the regulation and correct any unforeseen consequences.

This comprehensive surveillance system would monitor disease risks and profiles, and the prevalence of initiation, relapse and switching behaviour. In addition, a programme of continuous tobacco product surveillance should be established to enable regulators to keep up to date with product changes.

A new tobacco product of any kind, including new brands of cigarettes, should only be allowed onto the market if a comprehensive description of its characteristics and emissions is given (as described earlier) and if the manufacturer can demonstrate to the regulator that it offers the potential of reduced harm by comparison with currently available cigarette brands.

**Recommendation:** Any new tobacco product of any kind, including new brands of cigarettes must be given prior approval by regulators before entry to the market.

5. **Regulatory capacity in Europe**

A comprehensive and meaningful tobacco products regulatory strategy, such as the one set out above, can only be implemented if regulatory capacity is adequate, multi-disciplinary and well funded. This is currently not the case.

In most Member States, government regulation of tobacco control is handled by one or two civil servants and this task is often carried out alongside others, such as alcohol policy. A similar situation applies within the Commission, where tobacco-control policy is coordinated by a team within the Public Health Directorate, located within the Health and Consumer Protection Directorate-General. In practice, most tobacco actions at national and European level require the inputs of a number of other sectors in different parts of governments, such as trade, taxation and legal services.

A few Member States have set up dedicated national tobacco-control agencies. The Irish Office of Tobacco Control and the Norwegian Tobacco Control Agency in the Health Ministry are two such examples. In addition, other Member States have established scientific
committees of experts in tobacco control to provide advice and risk assessments, for example, the Scientific Committee on Tobacco or Health in the UK and the Tobacco Control Task Force of Iceland. The provisions of the EU Directive 2001/37/EC also provided for the establishment of a regulatory committee consisting of representatives nominated by the Member States, usually civil servants working on national tobacco policy. In addition, the EU Directive 2001/37/EC allows the Commission to be assisted by experts in the drafting of the report on its application.

However, even in those Member States with a larger than average staff contingent dedicated to tobacco control and even amongst the various scientific and regulatory committees that have been set up, the technical expertise needed to fully assess and regulate tobacco products is lacking. The complexity and sophistication of cigarettes and other tobacco products require a wide range of technical skills including toxicology, pharmacology, psychology and law. Those working on tobacco product regulation would need to work closely with those working on other areas of tobacco control, such as taxation and cessation policies.

Tobacco products differ from every other consumer product in that they kill half of all their consumers when used as directed by the manufacturer. However, they are no different in their need for regulation to food, pharmaceuticals and other consumer goods that enjoy far greater regulatory resources at national and EU level. Meaningful tobacco product regulation will require much greater and dedicated human and financial resources than is currently the case.

Increased capacity could be positioned alongside the current civil servants working on tobacco control both at Member State and at European Commission level. Alternatively, a dedicated European tobacco and nicotine products agency could be set up which could quickly build up relevant skills. The remit of such an agency could include all aspects of tobacco and nicotine product design, marketing and monitoring as described above. Staff drawn from a wide range of disciplines would initially be responsible for risk analysis and assessment. This is the most desired option and would put tobacco, correctly, on a par with the European agencies for drugs, medicines, and food products. According to the Treaty establishing the European Community, competence for regulation at European level lies with the European Commission and so the regulatory functions around tobacco products could not be transferred to an agency outside the Commission.

Until regulatory capacity can be increased, a multidisciplinary tobacco product regulation advisory committee should be set up at European level to advise on the development of the new staff and the short-term implementation of the regulatory recommendations outlined in this chapter.

Independent government laboratory capacity to test tobacco products is also lacking in the EU. Some laboratories have been closed down in recent years and others have been privatised.

---

b For example, cigarette testing used to be carried out by the Laboratory of the Government Chemist in the UK, but it is now performed by Arista, which is owned by Molins, a company with extensive commercial links with the tobacco industry.
In its most recent set of recommendations (yet to be published) the WHO TobReg has recommended that a series of regional laboratories be established to enable Member States to meet their product regulation obligations under the Framework Convention on Tobacco Control. One option would be for the EU to host an independent tobacco testing laboratory on behalf of itself and the WHO European region. The facilities offered by the Commission’s Joint Research Centre in Ispra, Italy, could serve as the basis for such a laboratory and offer additional research support to staff working on tobacco and nicotine product regulation in the future.

The costs of increased regulatory capacity should fall to the tobacco industry, for example through taxation or through a licensing system, but it is critically important that the regulators and regulatory process be completely independent from the industry.

**Recommendations:** Capacity to assess and regulate nicotine and tobacco products in the European Commission and Member States needs to be greatly increased and include the range of technical skills needed. At Member States level such staff could be housed in dedicated tobacco-control agencies (see also Chapter 7). At European level the preferred option would be for the establishment of a European tobacco and nicotine products agency. Until regulatory capacity can be increased, a multidisciplinary tobacco regulation advisory committee needs to be set up urgently across Europe to advise on tobacco regulation. The availability of independent laboratories to test tobacco products also needs to be increased.

The costs of increased regulatory capacity should be met by the tobacco industry but regulators and the regulatory process must be completely independent of all sectors of the tobacco industry.

**Acknowledgements**

With contributions gratefully received from Dr Wim Vleeming, Paul Nordgren, Dr Pieter de Coninck, Professor Martin Jarvis, Professor Dave Burns, Dr Lars Ramstrom, Dr Murray Kaiserman and Dr Ron Borland.


8 World Health Organization Study Group on Tobacco Product Regulation. Guiding principles of the development of tobacco product research and testing capacity and proposed protocols for the initiation of tobacco product testing (in press).


13 Smokefree Europe: conference on tobacco or health, Helsinki, Finland, 1996.


22 Irish Presidency/European Commission. 'Change is in the Air: Future directions in tobacco control in the EU (Limerick, Ireland, June 2004), www.otc.ie/Uploads/Conference%20Recommendations.pdf


37 McGuire A. How the tobacco industry continues to keep the home fires burning. *Tob Control* 1999; 8: 67-69.


