

Review of the implementation of the Tobacco Product Regulation Directive 2001/37/EC

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Executive Summary

'It is not so much their [new nicotine delivery systems being developed by the pharmaceutical industry] efficacy as temporary replacement to aid cessation, but their potential use for long-term self-administration which merits the most serious consideration..... It will be assumed throughout that our main concern is to reduce tobacco-related diseases and that moral objections to the recreational and even addictive use of a drug can be discounted provided it is not physically, psychologically, or socially harmful to the user or to others''

Professor Michael Russell, 1991

Introduction

This report reviews the implementation of the Tobacco Product Regulation Directive 2001/37/EC with a particular focus on the UK and makes recommendations for future developments in this area.

Context

Before examining the progress made so far and recommendations for future regulation, some general comments should be noted:

- The cigarette is a highly engineered and sophisticated nicotine delivery device. It is unlikely that any single test or measure will by itself be sufficient to use to regulate the harmfulness of cigarettes. Instead, an assessment of the harm and addictiveness of cigarettes will need to be made across a number of dimensions.
- There will never be a safe cigarette, as the process of combustion releases a host of toxic smoke components. Nevertheless, regulators and manufacturers are negligent if they do not utilise all knowledge at their disposal to reduce the harmfulness of cigarettes to the extent that this is feasible.
- Changes to the cigarette are likely at best to have only a marginal impact on the overall harm caused by cigarette smoking. Cigarette product modification should only be one part of a comprehensive tobacco control strategy focused principally on encouraging smokers to stop and on reducing initiation.
- Future tobacco product regulation must take into account the fundamental role that nicotine plays in tobacco use.
- Regulation should consider the range of nicotine delivery systems available, including therapeutic nicotine, with a view to ensuring that cigarettes and hand rolling tobacco for smoking are not the dominant forms of nicotine delivery on the market in 20 years time.
- From a public health perspective, the most promising nicotine delivery devices are those that are non-combustible. It is therefore hard to imagine a sensible nicotine regulatory framework which bans the use of regulated smokeless tobacco products and has strict

regulations on therapeutic nicotine delivery devices yet allows the unfettered use of cigarettes.

- Meaningful tobacco product regulation is very different from that currently called for by the tobacco industry.
- The regulation of the content and emissions of tobacco and nicotine products should not necessarily influence how they are marketed. Marketing of all tobacco and nicotine products should be under the strict control of regulators.

Progress made under the Directive to date

- The new tar machine based limit of 10 mg/cigarette is technically undemanding and is unlikely to result in any health benefits.
- Only two brands on the UK market in 2002 were above the *effective* nicotine limit (1mg/cigarette + 15% tolerance limit) set by the Tobacco Product Regulation Directive, so the vast majority of cigarettes on the market needed no modifications to meet the limit.
- It remains to be seen whether the required reductions in carbon monoxide (CO) yields will be achieved. In 2002, nearly 4 out of 10 brands were above the *effective* CO limit (10mg /cigarette + 20% tolerance limits) and selective reductions in carbon monoxide were necessary to achieve the limit.
- Tobacco companies are not complying with the requirements for ingredient disclosure.
- Article 8, the ban on oral smokeless tobacco, has been the subject of much debate within the UK and European Union with sharply polarised views on whether the ban should be revoked, and if so how.
- Misleading brand descriptors have been banned but some concerns remain about graphics and brand names still being used by some tobacco companies.
- Information concerning the harmful constituents of tobacco, the role of nicotine and the relative harms of different tobacco and nicotine products on the market has not been effectively communicated to consumers to date.
- The new bigger and bolder health warnings introduced through the directive already appear to be having an impact on smokers' behaviour. Preliminary evidence indicates that smokers are thinking about these warning levels and report forgoing cigarettes because of them.

Recommendations for future product regulation

- No further reductions in ISO machine-smoked tar and nicotine yields should be mandated, as such reductions can be achieved with cosmetic changes without any impact on health.
- It is too early to comment on whether the reductions in machine based CO yields are likely to be of value for public health. The wider tolerance limits set for CO yields suggest that tobacco manufacturers anticipated greater difficulty meeting the required limits. It is possible, *ceteris paribus*, that selective control of CO might have a positive public health impact but further research is necessary here.

- The ISO tests for machine-smoking should no longer be used as the main basis for cigarette regulation. These tests do not adequately reflect smokers' exposure to constituents and fail to take into account the role nicotine plays in smoking behaviour.
- 'Tar' should no longer be used as the basis for cigarette product regulation. Tar is not a homogeneous substance. Instead there should be a focus on particular constituents of tobacco and tobacco smoke.

The need for a comprehensive regulatory framework for tobacco products

- There is an urgent need to put in place a comprehensive framework for regulating the harmfulness of tobacco products (this must be done independently of the tobacco industry). Given the incomplete nature of knowledge about the harmful constituents of most tobacco products, the first step should be to ensure a comprehensive characterization of all tobacco products on the market, which is annually updated. This is a very large task and will require considerable resources. Data to be gathered should include the following:
 - Physical and chemical characteristics of products. This should include type of tobacco, content of tobacco, percentage of nicotine in the blend, type of filter and filter efficiency, filter ventilation, and pH. British Columbia and the Federal Government of Canada already have standard measurement tools to collect some of this information.
 - Ingredient disclosure. The tobacco industry is currently not complying with the current requirements for this. The World Health Organisation's Scientific Advisory Committee on Tobacco's (SACTOB) definition for ingredients should be used and the regulations strengthened to improve the toxicological information required from manufacturers. Over time, all additives should meet a test of public health or public interest or be withdrawn from use.
 - Emissions when the tobacco product is used by consumers. For smoked tobacco, this will include the quantity of constituents when smoked and their relationship to nicotine. Adaptations to the ISO testing to enable it to more closely approximate smoke delivery by smokers, such as using an intensive smoking regime and the capped tar to nicotine ratio, cannot accurately do so as no single puffing regime can reflect how smokers behave across the range of available brands. They should not be the only measurements for product regulation but could be informative if collected for a range of constituents on a regular basis. Precedents already exist in other countries. For example, measurement standards for testing a range of smoke constituents in mainstream and sidestream smoke using standard ISO and intensive machine smoking regimes already exist in Canada and have been used for regulatory purposes there since 1998.
 - Exposure of users and non-users to toxicants. Over time, a range of biomarkers for users of different types of nicotine delivery systems, and for non-users should be collected annually.
 - Addictiveness and addictive potential of the product. The dosage and speed of delivery of nicotine, abuse and dependence potential and other factors relating to the addictiveness of nicotine should be monitored across all nicotine delivery products annually.

- Disease risks. Epidemiological data should be monitored of the wide range of diseases known to be related to tobacco use with the aim of assessing harm associated with the use of different tobacco products over time.
- Population impact. There should be a comprehensive monitoring and surveillance system which could monitor the impact of any changes to tobacco on all aspects of consumer behaviour, particularly initiation, relapse, and quitting.
- Within a few years, regulators should move to set mandatory standards for the delivery of dangerous smoke constituents. In spite of incomplete knowledge, the precautionary principle can be invoked to require upper limits on certain known carcinogens. Given the uncertain public health outcomes of such a move, such standards should not be allowed to be communicated in any way to the consumer by the manufacturers. Instead the changes should be made mandatory. It will also be important to monitor the impact of setting such standards. The most appropriate way of setting the standards needs further elucidation. Upper limits could be mandated for emissions for known carcinogens and other toxins (for mainstream and sidestream smoke) based on median values produced using an intensive smoking regime for products currently on the market. These limits could then be progressively reduced over time. Alternatively, or in addition, upper limits for toxic and carcinogenic constituents per mg of tobacco (prior to combustion) could be set. It will be important to also characterise these constituents in relation to nicotine availability.
- Implementing the regulatory framework described above will require considerable financial and human resources, but the costs of doing nothing are enormous given the mortality and morbidity caused by smoking. Nevertheless, the fine grained quantitative regulation of cigarettes required above must not be allowed to consume vast time and resources of regulators at the expense of other proven effective strategies for reducing tobacco use and improving the qualitative regulation of the main different nicotine sources, namely tobacco and non-tobacco. The costs of regulation should fall to the tobacco industry, for example through taxation or through a licensing system. Monitoring and surveillance of the impact of the regulation will also be essential to ensure that consumers do not switch to other, no less hazardous, forms of tobacco use such as hand rolling tobacco, or alter their behaviour such as breaking off the cigarette filter to minimize the impact of any regulatory changes.

The need to regulate all nicotine delivery devices within a single framework

- This regulatory framework should be applied where appropriate to all nicotine and tobacco products including cigarettes, hand rolling tobacco, smokeless tobacco products and therapeutic nicotine products.
- Regulations need to take account of the growing use of hand rolling tobacco which is currently outwith most forms of product regulation
- Although not all the criteria apply to therapeutic nicotine products, assessing them within the regulatory framework would allow comparisons across nicotine delivery systems and enable a gradual shift of the market over time in favour of the least harmful products.
- A new tobacco product of any kind, including new brands of cigarettes, should only be allowed onto the market if a full characterisation of its constituents and emissions is given and if the manufacturer can demonstrate to the regulator that it offers the potential of reduced harm by comparison with currently available cigarette brands. Ultimately all existing tobacco products would also need to adhere to similar regulatory requirements.

- The most promising harm reducing products are non-combustible nicotine delivery systems which currently includes NRT and some smokeless tobacco products.
- If the ban on smokeless tobacco is removed, this should only be done within an evidence based regulatory framework which sets standards for carcinogens and other toxins in all forms of tobacco
- Steps should be taken to incentivise the production of clean recreational nicotine delivery systems.

Consumer information & packaging

- Consumer information needs to be improved. Currently inadequate and misleading information is given on packs of the most harmful tobacco products whereas comprehensive information is given on therapeutic nicotine products describing all the risks and potential side effects with no comparisons made with cigarettes.
- Health warnings on tobacco need to be refreshed regularly and should incorporate pictorial warnings when these become available.
- Tar and nicotine yields should be dropped from cigarette packs.
- The desired outcome of consumer information concerning tobacco products needs to be clarified. We suggest that it should be aimed at encouraging and facilitating smokers to successfully reduce their risks and quit smoking
- Information given about tobacco constituents and relative harm should be made as comparable as possible to that given by therapeutic nicotine delivery devices so that their relative harmfulness can be more easily understood. This should help to redress misunderstandings consumers have about the relative risks of these products.
- Options for how to improve consumer information are given but more research with consumers is needed before deciding the final format.
- The consumer has a right to know about changes or products offering a 'significant' reduction in harm. It has been suggested that a reduction in harm by one or two orders of magnitude could constitute a 'significant' reduction but this needs to be agreed by regulators. In the absence of long term epidemiological studies, there will be a large degree of error around any estimates of harm, hence it is very important that any consumer information communicating this reduction in harm should be under the strict control of a regulator who would specify the exact wording for such communications. This is particularly important in the light of mistakes with 'low tar' cigarettes. As a result all promotional bans on tobacco products should be maintained. Comprehensive surveillance of any communication of harm reducing messages would be needed.
- Generic packaging should be introduced for at the very least the most hazardous combustible tobacco products to negate the strong positive impact of pack designs.
- New traceable overt and covert markings enabling the place, date and time of manufacture are now being used on packs but are only decipherable by the tobacco industry. This goes against the spirit of the directive. Regulators should be able to decipher these codes without recourse to the industry. This will help regulators and the public to better understand and eliminate smuggling and counterfeit cigarettes over time.

The need for a regulatory authority

- A non ministerial government department, a Nicotine and Tobacco Regulatory Authority, similar to the Food Standards Agency, needs to be set up urgently in the UK. The complexity of the policy and regulatory responses needed to make significant changes in the nicotine market require much greater regulatory capacity than currently available and an authoritative, fully independent and properly resourced body is needed to oversee the regulatory framework and collect, analyse and assimilate the data provided by tobacco manufacturers and develop its own research, monitoring and evaluation programme.
- A similar body will also be needed at a European level to harmonise regulations across Member States. Precedents exist in other areas of public health for European bodies to be set up in the absence of similar bodies within all Member States
- A licensing system for manufacturers could provide the funding required for the regulatory bodies in UK and Europe.
- The new regulatory authority should encompass therapeutic forms of nicotine. If taking nicotine treatment products out of the medicines framework is resisted then one option could be for medicines regulators to still manage therapeutic forms of nicotine directly but share the information through a contractual arrangement or 'concordat' with the Nicotine and Tobacco Regulatory Authority.
- The scope of the new Nicotine and Tobacco Regulatory Authority needs to be determined. It could focus on product regulatory issues initially but we believe that ultimately it should take control of all aspects of tobacco control.
- Product regulation is an important aspect of the Framework Convention for Tobacco Control which the European Community and 21 countries in Europe have signed. Sufficient regulatory capacity and resources must therefore be devoted to this aspect of tobacco control.

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1. Introduction

This report discusses the implementation of the Tobacco Product Regulation Directive 2001/37/EC 1 with a particular focus on its implementation in the UK through The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 2. It aims to inform the review process set up by Article 11 of the Directive which specified the need for the European Commission (EC) to submit a report on the application of the directive. This report appraises the issues set out under Article 11 on the basis of the available evidence and makes recommendations for the way forward. It focuses predominantly on product regulatory issues.

Directive 2001/37/EC is a recast of the following three Council Directives:

- Directive 89/622/EEC, as amended by Directive 92/41/EEC. Both these directives established warnings for tobacco products (replacing voluntary agreements on labelling that had been in place since the 1970s) and the display of tar and nicotine yields on packs. The 1992 directive instigated a ban on certain types of tobacco for oral use.
- Directive 90/239/EEC. This established maximum limits for the machine measured tar yield of cigarettes marketed in Member States to 12mg. Previously in the UK there had been a series of voluntary agreements which had been concerned with progressively reducing the Sales Weighted Average Tar Yield (SWAT) of British cigarettes since the 1970s.

Directive 2001/37/EC included the following provisions:

- **Article 3** set maximum yields of nicotine (1mg/cigarette) and carbon monoxide (10mg/cigarette) and a further reduction in maximum tar yields to 10mg/cigarette from 1 January 2004. Greece was granted a derogation for the maximum tar yields until 1 January 2007. These limits could be applied to exported cigarettes from 1 January 2005 and had to be applied by 1 January 2007.
- **Article 4** stipulated that the yields should be measured on standard smoking machines to ISO specifications making reference to the ISO standards 4387, 10315 and 8454 for tar, nicotine and carbon monoxide respectively as well as ISO standard 8243 concerning the tar and nicotine indications on packs. Appendix 1 of this report details these ISO measurements.
- **Article 5** stipulated that the machine measured yields of nicotine, carbon monoxide and tar must be displayed on cigarette packs. This article also established new bolder, larger, black and white health warnings and traceable markings on tobacco packs enabling the place and time of manufacture to be determined.
- **Article 6** stipulated that a list of all ingredients and quantities thereof, used in the manufacture of tobacco products by brand name and type was required by 31 December 2002 and annually thereafter. The list had to be accompanied by a statement setting out reasons for inclusion of the ingredients indicating function and category and available toxicological data regarding the ingredients in burnt or unburnt form referring in particular to health and addictive effects. The data had to be disseminated to the Commission and to consumers (but without revealing trade secrets as appropriate).
- **Article 7** banned misleading descriptors and use of other signs (texts, names, trade marks and figurative or other signs) suggesting some tobacco products were less harmful than others, by 30 September 2003.
- **Article 8** banned tobacco for oral use (excluding smoking and chewing tobacco). Sweden was granted a derogation from this provision.
- **Article 9** stressed the need to adapt to scientific and technical process in measurement methods (in particular those given under Article 4), health warnings and identification markings

- **Article 10** stipulated that the Commission was to be assisted by a committee on the implementation of the directive.
- **Article 11** outlined that by 31 December 2004 and every year thereafter the EC was to submit a report on the application of the directive to the European Parliament, the Council and the Economic and Social Committee. They were to be assisted by scientific and technical experts in so doing and a number of areas were listed for attention in the report (these are itemised below).
- **Article 12** stipulated that by 31 December 2004 the EC be invited to submit a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, *inter alia*, their addictiveness.
- **Article 13** stipulated that Member States could bring in more stringent rules concerning the manufacture, import, sale and consumption of tobacco products. They could also provide for the prohibition of ingredients which increased the addictive properties of tobacco products, pending the establishment of the common list of ingredients.

Article 11

Article 11 listed the following issues needed to be considered in the EC's report on the application of the Directive, which we have grouped together into four main areas for consideration:

Methodologies for more realistically assessing and regulating toxic exposure and harm

- Subsequent reduction of the maximum yields laid down in Article 3(1)
- Possible links between these yields
- 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 carbon monoxide
- Development of standards concerning products other than cigarettes, in particular hand rolling tobacco

Ingredients

- Evaluation of the addictive effects of those ingredients which encourage addiction
- 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

Potential less harmful products

- Evaluation of tobacco products which may have the potential to reduce harm

Consumer information

- Improvements in health warnings, in terms of size, position and wording,
- New scientific and technical information regarding labelling and the printing on cigarette packs of photographs or other illustrations to depict and explain the health consequences of smoking
- Links between labelling requirements and consumer behaviour

Article 10 – Regulatory committee

This report will also summarise the published reports on the meetings of the regulatory committee set up to support the implementation of this directive.

The need for a regulatory authority

A consistent theme emerging throughout this report is the need for greater regulatory capacity in tobacco control, so an additional section has been added devoted to the need for increased regulatory capacity in the form of a properly resourced regulatory authority both in the UK and at a European level.

The report also references the Who Framework Convention on Tobacco Control (FCTC) now signed by 77 countries including 21 countries (and the European Community) in the Europe region. Product regulation is referred to in the FCTC and the relevant clauses are given in Appendix 2.

2. Context

A number of considerations need to be taken into account when examining the impact of the EU product directive.

First, the cigarette is a highly engineered and sophisticated nicotine delivery device. Many factors have been manipulated to increase the appeal of a cigarette to the consumer and are known to influence the toxicity and potential for nicotine addictiveness. These range from type and blend of tobacco used, ingredients added, how the cigarette is designed and manufactured, to how it is marketed and then smoked by the consumer ³. It is unlikely therefore that any single test or measure can be used on its own to regulate the harmfulness of cigarettes. Rather an assessment of the harm and addictiveness of a product will need to be made across a number of dimensions.

Secondly, cigarette smoking is such an inherently dangerous behaviour, that any alterations to the way cigarettes are manufactured or smoked are unlikely to have a hugely significant impact on mortality and morbidity. Whilst there is an obligation on regulators and producers to reduce the harmfulness of smoking as much as possible, it is important that this does not become the main focus of any tobacco control programme. It is extremely important that cigarette product regulation should be seen as just one component of a comprehensive tobacco control strategy which aims to prevent people starting to smoke, and most importantly to motivate and support smokers stopping.

Cigarette smoking is predominantly an addiction to nicotine and tobacco product regulation must take into account the fundamental role nicotine plays in tobacco use. Nicotine use has been in societies for many centuries and it is only with the advent of the manufactured cigarette that its use became so inherently harmful. Currently, the cigarette is the dominant form of nicotine delivery system in the UK and Europe, but a wide variety of nicotine and tobacco products are available around the world and more are being patented. It is therefore important to examine not just cigarettes, but all nicotine delivering products across the range of delivery systems from medicinal nicotine to smokeless tobacco products to cigarettes. Too much time and energy devoted to tinkering with the cigarette could mean that more promising avenues of harm reduction, which could have a much greater impact on public health, are ignored. The least harmful forms of nicotine delivery currently available are therapeutic nicotine replacement therapies but these are strictly regulated by medicines regulators with little regard to the other forms on the market. Non-combustible forms of tobacco are also less harmful than combustible forms but in the UK some types of non-combustible tobacco are banned. It is important to assess the role these products compared with both therapeutic forms of nicotine and combustible forms. Forms of nicotine delivery systems, other than those smoked, are discussed in detail in Section 3 of this report.

Some parts of the tobacco industry are also advocating regulation. For example, BAT's website claims:

'Given there are real risks of serious diseases associated with tobacco use, we believe tobacco should be regulated in various ways'

and Philip Morris's website:

'We support strong and effective tobacco regulation.'

Although Philip Morris go on to clarify what this means:

'We want regulation that will require all tobacco manufacturers to responsibly market their products to adult smokers, to communicate the public health community's messages about the health effects of smoking, and to implement measures that help prevent youth smoking. Strong and effective tobacco regulation can help achieve these goals'

In other words some parts of the industry would like regulation which enables them to continue marketing their cigarettes and communicating to consumers and to continue to run their youth campaigns, which are known to be largely ineffective (ref).

The only reference Philip Morris makes to constituents is under the heading 'Reduced risk products' and again the focus is on consumer information and communication:

'Such products could be defined in two ways: products that reduce the exposure to smoke constituents or products that reduce the risk of diseases caused by tobacco. Given a proper regulatory framework, consumers could be assured that they receive clear, factual, non-misleading information about these types of products'

The regulatory approach described in the present report are very different from the form of regulation requested by the industry. Regulation must be evidence based in favour of public health, not serving an industry agenda. This report outlines how regulation of the product should be independent of how the product is marketed and consumer information should be under the strict control of regulators. Separating the regulation of the product from its marketing would prevent a repeat of the light/mild branding fiasco. The terms of regulation must not be dictated by an industry which still gives little recognition of the inherent dangers of their products and has a history of misleading the public for example over the relative dangers of low tar cigarettes.

3. Methodologies for more realistically assessing and regulating toxic exposures and harm

Subsequent reduction of the maximum yields laid down in Article 3(1) and possible links between yields

Reduction in the machine-smoked tar yields of cigarettes was the key strategy for reducing the harmfulness of cigarettes in the last century. This section describes the trends in machine based tar, nicotine and carbon monoxide (CO) yields up to the present day and outlines what the changes that were needed to satisfy the directive. The public health impact of these changes is discussed in the following section. Detailed reviews have been published on these issues recently [4](#) [5](#) [6](#), the findings are summarized briefly here. In the last few years there has been a rapid evolution of the evidence regarding the impact of the tar reduction strategy and there is now a broad consensus that this has not had a positive impact on public health.

Tar yield reductions

In the UK since the 1970s, reductions in the Sales Weighted Average Tar Yield (SWAT) of cigarettes have been implemented through a series of Voluntary Agreements drawn up between the tobacco industry and the Government. This strategy followed recommendations from the Independent Scientific Committee on Smoking and Health (the government's then scientific committee) based on the understanding that tar was the principal carcinogenic and toxic component of cigarettes and reducing tar would reduce the likelihood of smokers developing cancers and other diseases. Subsequently, EU regulations have progressively reduced the permissible machine-smoked tar yield of manufactured cigarettes.

Hence in the UK, sales weighted average tar yields declined from 33 mg/cigarette in 1934 (plain cigarettes) to 21 mg/cigarette in 1972 (filter cigarettes) [7](#) and to 9.5 mg/cigarette in 1999 (filter cigarettes) [8](#). Figure 1 shows the trends since 1972. Data are available for plain cigarettes throughout and indicate a higher sales-weighted average tar yield at any point in time.

Of the 187 cigarette brands on the market in the year 2002 [9](#), 94 (50% were over the proposed 10mg/cigarette limit. The testing regime allows for a 15% margin of error thus making the effective limit 11.5 mg/cigarette. Using this cut-off, 39 brands (21%) were above in 2001 and would need to have their yields reduced by 1 January 2004. However, as described in the next section, achieving the new limit across all brands will pose few problems for the industry.

Nicotine yield reductions

No limits or reductions were set for nicotine yields until the most recent directive (which set an upper limit of 1 mg/cigarette by 1 January 2004). Nevertheless, as the machine based tar yields declined, to a large extent so did the machine based nicotine yields (see Figure 1). Techniques such as increasing the ventilation of the filter affected the nicotine readings on the cigarette testing machines in a similar way to the tar yields.

Figure 1. Reduction in sales-weighted machine based tar, nicotine and carbon monoxide (CO) yields in UK manufactured cigarettes since 1972
Source: Jarvis (2001)

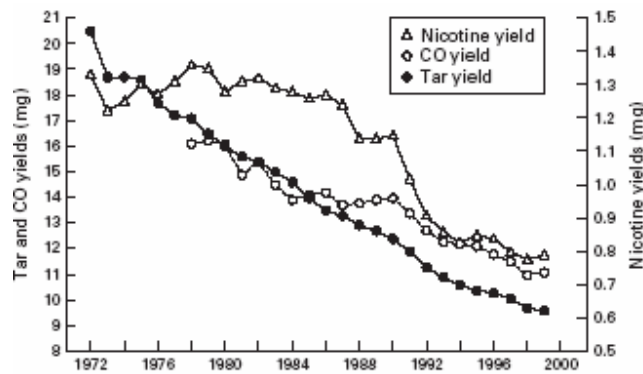


Figure 1 Sales weighted mean tar, nicotine, and carbon monoxide yields (mg/cigarette) of UK manufactured cigarettes 1972-99.

In 1934, sales-weighted average nicotine yields are estimated to have been 2.0 mg/cigarette rising to 2.2 mg/cigarette in about 1950 but then fell to 1.3 mg/cigarette by 1980 7. Between 1980 and 1986 however, there was little change in the sales-weighted average nicotine yields but then there was then a substantial decline to <1mg/cigarette in 1994 (a small part of this was attributable to changes in the way the measurements were taken in 1991). The decline has continued since 1994 but at a slower rate. By 1999 the sales weighted mean was 0.79 mg/cigarette 8. From the 2002 cigarette brand data 9 only two brands were over the effective 1.15 mg/cigarette limit (10mg + 15% tolerance) specified in the directive. These brands also had the highest tar yields for all brands in that year.

The ratio of tar to nicotine machine based yields illustrates the link between the yields. Some experts had advocated a reduction in the tar relative to nicotine (see below) and although this was never adopted as an explicit strategy by government, reductions in the average SWAT/nicotine ratios were tolerated and these declined between 1972 and 1987 (see Figure 2). Although the ratio declined steadily from a value of 15.4 in 1973 to a value of 10.6 in 1986, there was then an increase to 12.5 in 1993/4 with a subsequent plateauing around 12 8. However, Jarvis calculated that sales weighted tar to nicotine ratios were some 22% lower in 1999 than in 1972. When the low tar brands were introduced they had higher tar to nicotine ratios than the other brands, but that this had quickly reversed and since that time have had considerably lower tar to nicotine ratios than the other brands, the difference in the ratios between low tar and other brands in 1999 amounting to 14%.

Carbon monoxide yield reductions

This directive set a limit for CO for the first time. CO yields have however been decreasing in parallel with nicotine and tar yields. Although the sales weighted average carbon monoxide yield rose from 18.6 mg/cigarette in 1934 to 20.6 mg/cigarette in the late 1950s, it then declined to 14.7 mg/cigarette in 1985 (see Figure 1). Declines since 1978 were at a rate similar to tar yield decline but in 1985 they then diverged 8 with a slower decline to an average figure of 11.1mg/cigarette in 1999.

Figure 2 Sales weighted mean tar to nicotine ratios in low tar brands, other brands, and all brands combined From Jarvis (2001) 8

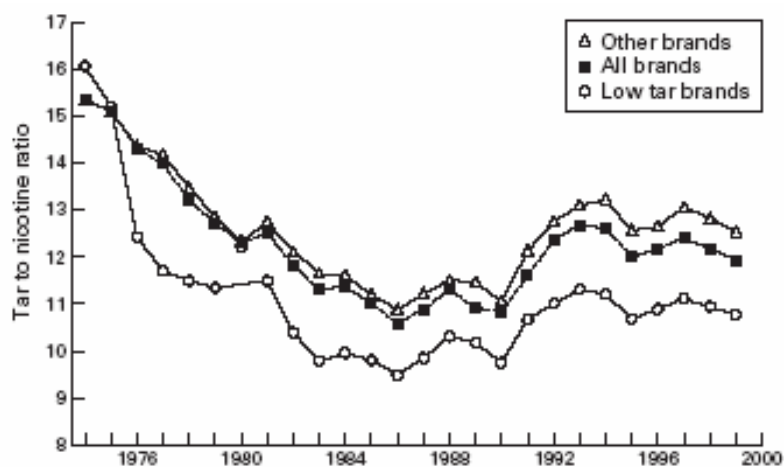


Figure 2 Sales weighted mean tar to nicotine ratios in low tar brands, other brands, and all brands combined.

The tolerance limit for CO yields is set somewhat higher than those for tar and nicotine at 20%, giving an effective upper limit of 12mg/cigarette. From the 2002 data 93 (50%) brands were over the limit of 10mg/cigarette and 72 (39%) over 12 mg/cigarette. The divergence from tar yields suggests that manufacturers will need to make selective reductions of carbon monoxide to achieve the target.

Failure to take account of smoking as nicotine seeking behaviour

The main problem with the reduction in tar yields strategy has been that the tar yields are measured using cigarette smoking machines which do not measure what consumers ingest from their cigarettes because people do not smoke like machines. This section explains the machine tests and the drawbacks of using them to regulate cigarettes.

Tar is defined as the cigarette smoke condensate or total particulate material (TPM) 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 microgram are trapped with 99% efficiency, but the gas or vapour phase of the smoke passes mostly through the filter. These machine tests were introduced by the US Federal Trade Commission (FTC) and adopted by the International Standards Organisation (ISO) and set parameters for the machines (see Table 1).

Table 1 Parameters of the standard ISO test

Puff Volume	35 ml
Puff Interval	1 per minute
Puff Duration	2 seconds
Butt length	23 mm for nonfiltered and 3mm above filter overlap for filter tipped cigarettes. (There are slightly different specifications for butt length for the FTC test).

Manufacturers achieved the reduction in machine measured tar yields using several techniques:

- Increasing the ventilation of the filter
- Increasing burn rate
- Decreasing tobacco density
- Increasing the porosity of the wrapping paper
- Changes in tobacco blending
- Changes in filter efficiency eg pressure drop alterations

However, the main method used was to dilute the smoke through placing ventilation holes in cigarettes filters 10. This resulted in air also being drawn in through the filter causing in a reduction in the machine-registered yields. Both gas and particulate yields were reduced roughly in proportion to the degree of ventilation.

However, as most smokers regulate their nicotine intake to maintain a relatively constant intake of nicotine each day, they alter the way the 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 unintentionally. Cigarette testing machines cannot take account of this relationship between nicotine intake and behaviour as the machine puffing patterns are standardized and the ventilation holes cannot be covered. The 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 5.

Machine delivered measurements differ greatly from smoke intake measures from smokers. An illustration of this is given in Figures 3 and 4. Jarvis and colleagues 11 showed that in a representative sample of smokers in England there was a very wide range in intake differences ranging from just above 0 to 50 nicotine mg per day for cigarettes having the same machine yields. Actual intakes differed greatly from the predicted intakes and were broadly similar across the range of machine delivered nicotine yields

Fig 3:

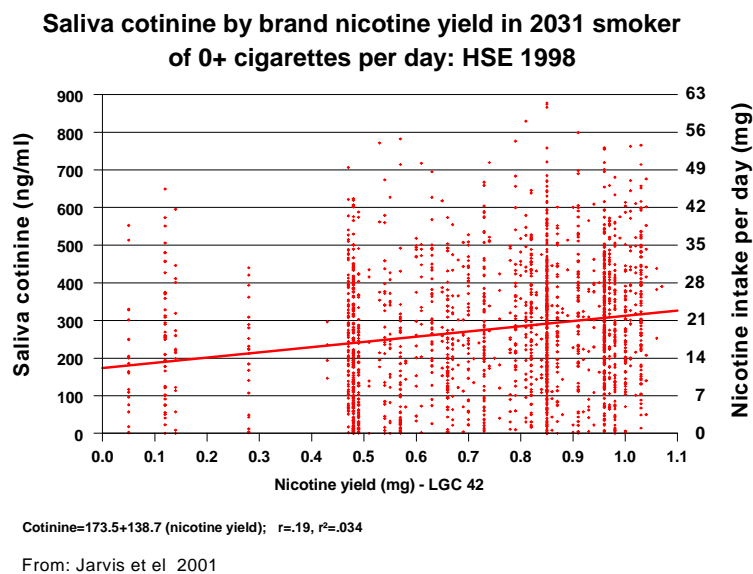
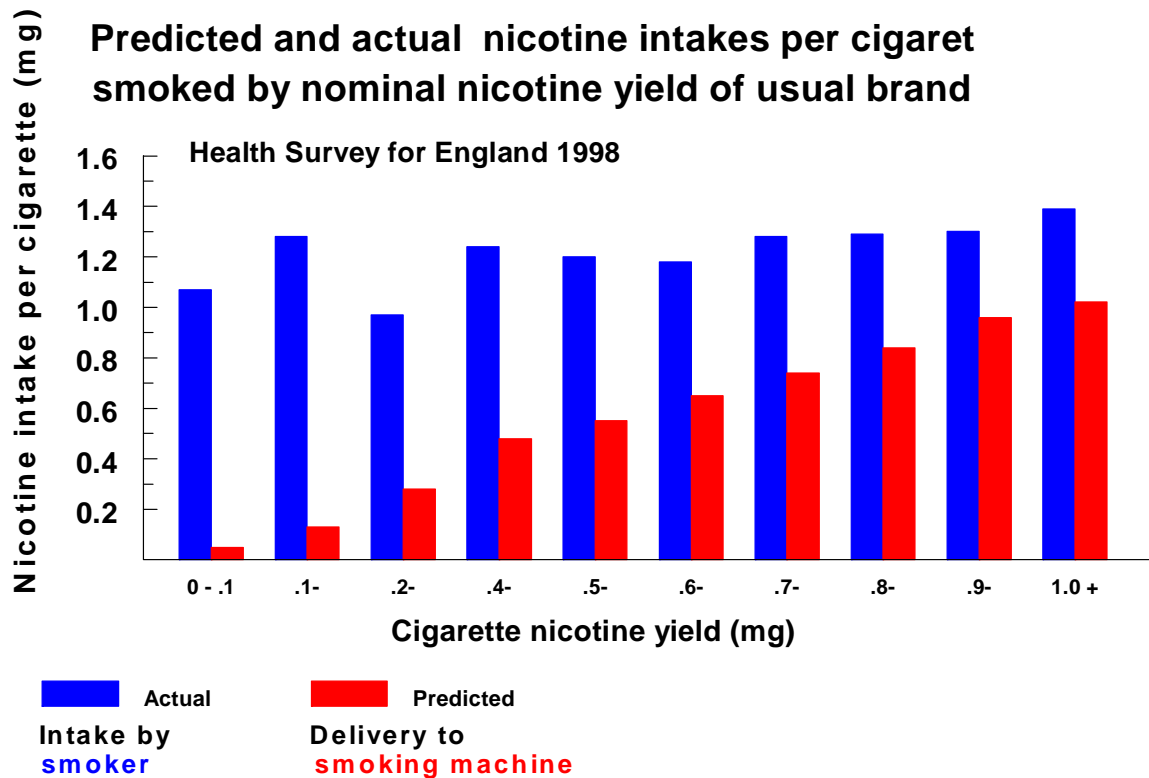


Figure 4:



From: Jarvis et al 2001

The concept of 'tar' is misleading

The second problem with the reduction in tar yield approach is around the concept of 'tar'. More than 2,000 chemical constituents exist in tobacco and about twice that number when tobacco is burned during smoking 6. 'Tar' has markedly different compositions across different products and across different countries. Hence the concept of tar as a single homogeneous toxic substance is very misleading.

Hoffmann has demonstrated how trends in the concentrations of different carcinogens within tobacco smoke change differently and independently of tar over time 12 13. Since the 1950s, as tar yields have been reducing, Hoffman tested an unnamed brand of non-filter US cigarette for two carcinogens Benzo[a]pyrene (BaP) and 4 – (methylnitrosamino) -1-(3-pyridyl) -1- butanone (NNK). BaP decreased between 1965 and 1975 and then plateaued with a further dip in the early nineties. NNK however, did not correlate at all with tar yields and increased between the late 70s and early 90s.

The concept of 'tar' is therefore outdated and needs to be replaced with a more sophisticated understanding of the different constituents of tobacco and/or smoke.

Public health impact of reductions in yields

There is now a broad recognition that the ISO/FTC standard measurement methodology is inappropriate as a basis for regulating the harm done by cigarettes. Reductions in machine-smoked tar yields can be achieved relatively easily by cosmetic changes to the cigarette, and together with compensatory changes in smoking behaviour, these do not result in differences in exposure to the smoker. These superficial changes have had little or no bearing on the mortality and morbidity caused by smoking. Although in the UK lung cancer rates have decreased over the last few decades, there are many competing explanations for the decline, such as the decline in prevalence, some qualitative change in the tar which has lowered its carcinogenicity and the introduction of reconstituted tobacco sheets in the manufacture of cigarettes. Indeed, despite reductions in machine based tar yields in the US no corresponding decrease has been found in lung cancer rates.

Tobacco industry documents released through litigation in the United States reveal that the industry knew about compensation since the 1970s but chose to deceive their customers into believing that low tar cigarettes offered a health benefit [14](#). Some tobacco companies are now agreeing publicly that smokers should not assume lower tar cigarettes are safe or safer than other brands (see for example Philip Morris website [15](#)).

Recent reviews of the evidence have concluded that there is no convincing evidence of any benefit to public health from reductions in tar yields [4 5](#). The RCP stated:

'harm reduction strategies based on naïve interpretation of tar and nicotine yield measurements should be discontinued. In practical terms, this means abandoning the strategy of seeking lower nominal tar yields and instead finding approaches that genuinely reduce harm to nicotine users'

The ban on misleading descriptors such as light, mild etc, based on the tar ratings in Article 7 of the directive illustrates that the ISO based measurements have already been accepted as misleading.

Given that CO yields have been decreasing for some time, it seems unlikely that the new limit in itself will result in a significant impact on public health. However, if meeting the limits requires companies to develop new or different technologies there could be some benefit. However, it will be important to establish that declines in CO are not achieved at the price of adverse changes in other smoke components.

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 does not cause most of the harm.

Risks of nicotine

There exists a large body of evidence that nicotine is not a significant risk factor for cardiovascular events, does not cause cancer and does not cause respiratory diseases such as emphysema. Although there is some evidence from *in vitro* and *in vivo* studies with mice that some metabolites of nicotine can be transformed into nitrosamines or that nicotine might stimulate angiogenesis and promote tumour growth and atherosclerosis in mice, there is no evidence of this happening in people using nicotine replacement therapies (NRT). There is now a great deal of experience with NRT products in the US and the UK and the evidence indicates clearly that the products are safe.

There remain concerns about nicotine safety in pregnancy. Nicotine crosses the placenta and is a potential fetal teratogen. Nicotine may contribute to obstetric complications in pregnant women and has been implicated in low birth weight and in sudden infant death syndrome.

Should nicotine be reduced?

In 1994, Benowitz and Henningfield suggested that reductions in nicotine bioavailability to a non-addictive level would virtually eliminate smoking, a proposal subsequently extended and supported by the same authors together with American Medical Association [16](#). The EU cancer experts committee also advocated a reduction in machine measured nicotine yields to 0.5mg [17](#).

However, there are fundamental problems with such a nicotine reduction strategy - most notably that smokers will compensate for the reduction in nicotine by altering their smoking behaviour to ingest more smoke to attain the nicotine dose they are seeking. In addition there are risks of an expansion in the smuggling of higher nicotine cigarettes. Some of these concerns were acknowledged by the authors but were not considered to be fatal flaws in their strategy.

Given the important role of nicotine, it is equally plausible for regulators to consider maintaining a sufficient nicotine dose alongside a reduction in toxins. This strategy recognises that nicotine is not responsible for the burden of smoking related disease and that regulatory attention should be focused principally on reducing the emissions of the unwanted toxic components of the smoke. At one extreme, such a strategy could tolerate the use of recreational nicotine in society providing it does not harm others and is at minimal risk to the user.

The need for cleaner nicotine systems to be more accessible

There are some commonalities between the nicotine reduction and nicotine maintenance approaches highlighted above. Both recognize the need for cleaner nicotine delivery systems to be available and as easily accessible, or preferably more, than cigarettes.

Regulating nicotine is therefore important in being able to shape the nicotine market. The nicotine limit implemented through this EU directive, an important harmonization measure, has, in principle, brought the nicotine delivery of cigarettes under regulatory control. The WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTOB) acknowledged that a broad and comprehensive regulatory framework was required to enable policy options for controlling nicotine to move forward in ways that minimize the risks [18](#).

Freebase nicotine

That cigarettes have been engineered and manipulated to increase their addictiveness is evident from tobacco industry documents [14](#). One area of current debate concerns the extent to which the industry strove to increase the percentage of freebase nicotine delivered to smokers [19](#) and this is discussed briefly here.

Freebase nicotine (also known as unprotonated or unbound nicotine) is more volatile than protonated nicotine (salt or bound nicotine). Although it has been hypothesized that freebase nicotine is more rapidly absorbed by the smoker thereby making it more addictive (as speed of absorption has been shown to be related to the addictiveness of nicotine [5](#)), this needs further research. Freebase nicotine would increase nicotine absorption by the buccal cavity and upper respiratory tract but these methods of absorption are slow compared to the lung. However, it remains possible that these types of absorption might be related to sensory perceptions of the 'impact' of the smoke, as it has been referred to by some tobacco companies, which could be related to the addictiveness of the product.

The proportion of freebase nicotine can be manipulated by altering the pH of the smoke [14](#). The pH of cigarette smoke has been estimated by the industry to be typically between 5 and 6 [20](#). The

proportion of free nicotine is affected by the type of tobacco with air-cured tobaccos and blended cigarettes having lower sugars than flue-cured cigarettes and therefore a less acidic smoke. This would result in a greater proportion of free-base nicotine in the smoke. It has also been established that ammonia converts protonated to free-base nicotine [19](#).

Whether the pH of the smoke affects absorption needs to be further researched. The tobacco industry argues that the thermal energy resulting from the burning cigarette could cause the conversion from protonated to unprotonated nicotine irrespective of the amount of ammonia or the pH of the smoke. When tobacco smoke reaches the lower respiratory tract and lung alveoli nicotine is rapidly absorbed and it remains possible that the pH of the smoke has little or no effect on the amount and rate of lung absorption.

Recommendations

- There should be no further reductions in machine based maximum tar/nicotine yields
- It is too early to comment on the potential impact of the new limit on CO yields
- ISO tests should no longer be used as the basis for cigarette regulation
- ‘Tar’ should no longer be used in the regulation of tobacco products but be replaced with different constituents of tobacco and/or tobacco smoke
- Future measurement tools should take into account the role of nicotine in tobacco use
- Cleaner nicotine delivery systems should be made more accessible than cigarettes and other forms of combustible tobacco
- It is important to have nicotine under regulatory control and the limit of 1 mg/cigarette nicotine yield is an important first step in this process
- Further research is needed as to whether the proportion of freebase nicotine affects the addictive properties of tobacco products and its relationship to ingredients and additives

Methodologies for more realistically assessing and regulating toxic exposure and harm

To date, regulation of the product has focused only on one aspect of the cigarette, emissions, and only on emissions to machines rather than to smokers during actual use. Some suggestions have been made to alter and improve the machine based tests to match more closely smoking behaviour in order to improve our understanding of emissions to smokers. This will be discussed in the relevant section below.

The complexity of cigarettes indicates that regulation to reduce their harmfulness will need to focus on a number of dimensions and be grounded in a proper understanding of smokers’ behaviour. It is important to increase our understanding of the actual exposure of smokers to toxins and nicotine and the impact of this on their health. The WHO SACTOB [21](#) has 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.”

The following dimensions would therefore need to be assessed as part of a comprehensive regulatory framework for tobacco products and this relates broadly to categories highlighted by WHO SACTOB 3:

- Physical and chemical characteristics
- Emissions when actually used by the consumer
- Exposure - uptake of toxicants by smokers and non-smokers
- Addictiveness and addictive potential of the product – uptake of nicotine
- Disease risks
- Consumer behaviour (including initiation, relapse, quitting)

Assessment of these other factors is still largely in its infancy and only some of the key issues are addressed below. The complexity and sophistication of the cigarette will require technical and specific skills which are largely lacking among regulators and tobacco control experts around the world. In addition, the marginal impact on public health of regulating some of the characteristics of cigarettes needs to be remembered, since, as discussed above, too much time and energy devoted to regulating cigarettes could draw attention away from other more promising harm reduction avenues discussed more in Section 5.

This regulatory framework should apply to all types of nicotine delivery systems including nicotine replacement therapies which are currently regulated separately by medicines regulators. This is also discussed in more detail in Section 5.

A new regulatory framework for assessing and regulating the harmfulness of cigarettes

Physical and chemical characteristics

There are many aspects of the design and make up of cigarettes that affect exposure to tobacco constituents and the harm caused by smoking. This section only briefly describes these issues and the reader should refer to the recent Institute of Medicine report for more details. There are some immediate steps that regulators in Europe can take to ensure that they have a full characterization of the products on the market today similar to the reporting requirements already in place in British Columbia and throughout Canada 22.

The key physical and chemical characteristics of cigarettes that need to be considered are:

* *Types of tobacco*

The type of tobacco used in cigarettes changes over time. Originally British cigarettes were only flue-cured (bright of Virginia tobacco), but US blended type of cigarette (mixture of flue-cured, Burley (air cured) and Oriental tobacco) are becoming more popular. The use of processed tobacco (reconstituted tobacco and expanded tobacco) has also become more popular over time. Different blends of tobacco influence smoke yields and smoke constituents.

* *Content*

For example, nitrates in tobacco affect nitric oxide in the tobacco and pH of smoke. There has been a gradual increase of the nitrate content of the tobacco blend causing lower yields of PaH in smoke but increases in NNK and other TSNAs. Health Canada 22 has an extensive reporting system for every constituent per mg of tobacco, paper, tube or filter in cigarettes.

* *Type of filter*

Cellulose acetate filters are used almost exclusively in the UK and throughout most of Europe. These remove some of particulate phase of smoke (depending on particle size), particularly

volatile nitrosamines and up to 80% of semivolatile phenols. Charcoal filters, popular in Japan and a few other countries such as Hungary, selectively remove a range of vapour phase components. The taste of the cigarette can change with the filter material used which is why the choice of filter is regionalized. British Columbia requires information on the type of filter on a regular basis.

* *Filter ventilation*

Ventilation is the key determinant of machine based smoke yields. Gray and Kozlowski 23 have suggested ventilated filters be banned given that without them compensation would be more difficult. However, it is questionable whether this is needed or appropriate if yields are not reported on the sides of packs and descriptors based on the machine yields are banned. Banning ventilated filters might make cigarettes more harmful as yields would rise and low nicotine brands could only then be engineered through manipulating the blend of nicotine/tobacco. At this time, it is difficult to identify what the consequences for smoking behaviour and public health might be.

* *Pressure drop*

This is related to smoke removal efficiency and consumer acceptability and is also referred to as 'resistance to draw'.

* *pH of cigarette smoke*

As mentioned above, this affects the proportion of nicotine which is free base which in turn is hypothesized to influence absorption into the blood stream. The pH can be made more basic by the addition of ammonia. British Columbia and Health Canada request this information regularly from cigarette companies.

* *Type of cigarette paper used*

This is highly engineered and the industry claims it can influence overall product performance more than any other non-tobacco component 24. Factors such as permeability, weight, thickness, strength etc all play a role.

* *Dimensions of cigarette and tobacco rod*

The physical characteristics such as the weight and density of tobacco all play a role in smoke emissions.

* *Proportion of nicotine in the blend*

It is important to measure the proportion of nicotine in the tobacco blend. Concerns have been expressed that tobacco strains which have been genetically engineered to raise their nicotine content and that these could potentially be more addictive. However, such strains of tobacco may result in smokers achieving a satisfying dose of nicotine with a reduced smoked intake. Nicotine is an irritant and tobacco blends with higher nicotine levels may be more aversive to consumers. By measuring the proportion of nicotine in the tobacco blend these hypotheses can be explored further. It would appear that Health Canada routinely collect alkaloids in whole tobacco which would enable an approximation of this measure to be assessed 25.

Emissions when actually used by the consumer

The WHO SACTOB define emissions for smokeless tobacco and cigarettes 21 as:

'In the case of smokeless tobacco products, emissions refer to substances released during the process of oral use ("chewing"). In the case of the cigarette and other smoked products, the term refers to the constituents of the smoke. This includes those emissions directly inhaled by the user of the product ("mainstream smoke") and those inhaled by nonusers and users alike ("secondhand tobacco smoke").'

Two main suggestions have been made to the machine tests to make them more closely mirror smoking behaviour and the emissions delivered when in actual use. These involve changing the parameters of the machine to make it more closely mimic smoking behaviour by more intensely smoking the cigarette, and using the ratio of the standard ISO tar and nicotine yields or of more intensive smoking regimen yields as an indicator of potential harm. These are discussed further below.

Emissions directly inhaled by the user of the product

Intense machine smoking regimes

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 which *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 (see Table 2). The Modified ISO test was designed to assess the maximum yields of a cigarette that could be made available to a smoker.

Table 2 British Columbia modified ISO conditions (from BC Website)

	Standard ISO	Modified ISO (1) (Used for the 1998 & 1999 reporting years)	Modified ISO (2) (Used for the 2000 and beyond reporting years)	Massachusetts modifications
Puff Volume	35 ml	56 ml	55 ml	45 ml
Puff Interval	60 seconds	20 seconds	30 seconds	30 seconds
Puff Duration	2 seconds	2 seconds	2 seconds	2 seconds
Ventilation Holes	not blocked	fully blocked	fully blocked	50% blocked

Health Canada subsequently adopted the Modified ISO (2) test method in their Federal Tobacco Reporting Regulation 22 and required both standard and modified measures to be made available to consumers on packs in the form of a range (see later).

The Massachusetts Department of Health proposed reporting requirements for smoke constituents using a further modification of the ISO test which used 50% vent blocks, 45 ml puff volume and 30 seconds puff interval in 1998 (see Table 2) but this has not yet become legislation. Their philosophy was not to obtain a maximum yield but a more realistic estimate of the yield to an average smoker.

Altering the machine smoking tests to intensify smoking behaviour has resulted in higher yields of nicotine and specific lung carcinogens being delivered 27. However, the fundamental drawback with these tests is that no uniform protocol can represent actual smoker behaviour, since the extent to which smokers puff and inhale varies systematically with characteristics of the cigarette such as the extent of filter ventilation. Nevertheless, the Modified ISO test adopted by Health Canada is informative as it should theoretically provide a maximum amount of smoke which could be delivered to the smoker.

Tar/nicotine ratios

An alternative adaptation of the ISO tests was proposed by Professor Michael Russell in 1976. He suggested that cigarette smoking could be made less hazardous by reducing tar and other toxins relative to nicotine 28. This was based on the fact that smokers tend to regulate their nicotine intake so it would be favourable to reduce the quantity of toxins for a given dose of nicotine, over time.

However, the tar/nicotine ratio is also dependent on how the cigarette is smoked. In 1986 Rickert and colleagues 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 29.

Ramstrom 30 suggested that intense and standard ISO techniques resulted in quite similar tar/nicotine ratios across a range of tar yields (see Table 3) although he acknowledges these findings were based on Canadian cigarettes which have a wider range of tar yields than those cigarettes available in Europe today.

Table 3: Tar /nicotine ratios under standard (red) and intense (blue) smoking regimes
Source: Ramstrom, 2003

du Maurier King Size	du Maurier Light King Size	du Maurier Regular	Player's Regular	Player's Light Regular	Player's Extra Light Regular	Player's Light King Size	Matinee Extra Mild King Size	Rothmans King Size	Export A Regular	Export A Light Regular
11	10	12	11	11	10	10	10	11	11	11
11	11	12	11	11	11	11	12	12	11	12

More recently, the Laboratory of the Government Chemist (LGC, 2000 31) tested 12 cigarette brands available on the UK market in 1999 using standard, British Columbia and Massachusetts modified testing ((1) on table 2) regimes. Table 4 details the findings of this study giving the tar and nicotine yields and the tar/nicotine ratios for each testing regime. The final two columns show the relationship between the tar/nicotine ratios between the two modified testing regimes and the ISO tests separately.

The findings illustrate that with today's cigarettes, the differences between the tar/nicotine ratios for the British Columbia intense smoking protocol and the standard ISO test are quite significant (particularly for cigarettes with lower ISO tar yields). The differences between the tar/nicotine ratios for the Massachusetts testing regime and standard ISO test are more closely approximated.

The ratios do indicate the misleading nature of the lower yielding brands which have better tar to nicotine ratios than higher yielding brands when using the standard ISO tests, but with very intense human smoking regimens the tar to nicotine ratios from lower yielding cigarettes get considerably worse sometimes indicating greater tar per dose of nicotine being delivered than with the higher tar yield brands.

However it is worth noting that the ratios vary considerably less than the actual tar yields (which can vary by 30 fold) so the ratio metric may have more validity and its utility rests on the need to view smoking as nicotine seeking behaviour. Ramstrom (personal communication) therefore continues to argue that the ratio metric is the only meaningful way of regulating tobacco products.

Table 4 – Tar and tar/nicotine ratios of a selection of UK brands using the standard ISO machine tests, and the more intensive British Columbia (BC) and Massachusetts (Mass) smoking regimes

	ISO Tar	ISO Nic	ISO T/N	BC Tar	BC Nic	BC T/N	Mass Tar	Mass Nic	Mass T/N	ISO/BC T/N	ISO/Ma T/N
Silk Cut Ultra KS	1.01	0.11	9.18	31.18	1.95	15.96	9.11	0.84	10.89	1.74	1.19
Mayfair Ultra KS	1.19	0.12	9.92	30.34	1.80	16.87	8.97	0.79	11.37	1.7	1.15
Silk Cut Ex Mild KS	2.91	0.29	10.03	32.73	2.04	16.1	12.86	1.14	11.31	1.6	1.13
Superkings Ultra	3.36	0.31	10.84	28.77	1.70	16.97	11.18	0.94	11.91	1.57	1.1
Red Band Lights S/K	5.73	0.53	10.87	40.16	2.56	15.66	18.30	1.46	12.57	1.44	1.16
Embassy Ex Mild KS	7.8	0.70	11.14	33.51	2.30	14.57	19.34	1.63	11.86	1.31	1.06
Balmoral Lights KS	8.09	0.64	12.64	36.9	2.35	15.69	19.78	1.51	13.08	1.24	1.03
Superkings Lights	8.29	0.82	10.11	37.03	2.90	12.8	20.57	1.97	10.42	1.27	1.03
Benson & Hedges KS	10.66	0.85	12.54	39.91	2.64	15.13	24.33	1.89	12.89	1.21	1.03
Rothmans KS	11.02	0.95	11.6	41.48	3.03	13.67	24.7	2.19	11.26	1.18	0.97
Marlboro KS	12.01	0.86	13.97	45.31	2.71	16.73	27.86	1.95	14.26	1.2	1.02
Raffles 100's	12.36	1.10	11.24	42.45	3.52	12.08	26.84	2.47	10.89	1.08	0.97

Capped tar/nicotine ratios

Bates ³² and Ramstrom (personal communications) have proposed setting a limit to constrain possible combinations of high tar and high nicotine yields. He suggested a ratio of 10 (together with the current tar and nicotine yield limits). This is referred to as the capped ratio approach. Assuming the tolerances were allowed in the measurements used in the construction of such a ratio, the ratio of 10 could in the extreme become $(10+1.5)/(1-0.5) = 13.53$. Given the resulting much greater tolerance, Bates proposed a maximum tolerance of 15% for the calculation of the ratio ie a maximum ratio of 11.5.

From the 2002 data, 120 brands (64%) were over this limit. Introducing such a measure would therefore impact on many more brands than are currently affected by the EC directive.

Such a limit could also be applied to the Modified ISO tar/nicotine yields, but currently this would mean that most brands would not comply (if the BC modification was used).

The problem with the ratio measurement is again the inability of a limited number of machine protocols to represent actual smoker behaviour. In addition, these ratios still rely on the construct of tar. The capped ratio is a promising approach but may need to be applied to different toxins and their relationship to nicotine as discussed further below.

A two-stage compensating test

Kozlowski and O'Connor (2000) ³³ suggested that a two-stage compensating test could be used which allowed for compensatory smoking at lower yields. This system would be an improvement on the existing standard/intensive ISO machine testing regimes and could be used to estimate more meaningful tar/nicotine ratios. This metric therefore has merits but the authors themselves argue that it would not allow for individual differences in smoking behaviour and may still underestimate compensation.

Elasticity of cigarettes

Elasticity is the amount of smoke a smoker can take out of a cigarette. It can be applied to any smoke constituent or ratio of constituents. One formula for measuring elasticity is given on the Physicians for a smoke free Canada website:

$$\text{Elasticity} = (N2/P2) \times (P1/N1) \times (V1/V2) \text{ 34.}$$

where:

- V1 = puff volume of 44 ml
- V2 = puff volume of 56 ml
- N1 = delivery in mg at 44 ml
- N2 = delivery in mg at 56 ml
- P1 = number of puffs at 44 ml
- P2 = number of puffs at 56 ml

A cigarette with elasticity over 1 is said to be elastic and indicates that the increase in the chemical constituent is proportionally greater than the puff volume. The analysis of Canadian Brands has indicated that whereas less than a quarter of the brands tested were elastic, these cigarettes accounted for two-thirds of the sales, suggesting that cigarette brands which were more elastic and hence more effective nicotine delivery devices were more successful 35.

Applying this to the British cigarettes (Kozlowski, personal communication – see Table 5) used in the study above shows that all the cigarettes were elastic but that the lower yielding cigarettes had much greater elasticity.

Table 5 – Elasticity of British cigarettes (from Kozlowski, personal communication)

	ISO Tar	ISO Nic	Elasticity Mass vs ISO	Elasticity BC vs ISO
Silk Cut Ultra KS	1.01	0.11	3.85	9.11
Mayfair Ultra KS	1.19	0.12	3.35	7.73
Silk Cut Ex Mild KS	2.91	0.29	2.05	3.47
Superkings Ultra	3.36	0.31	1.38	2.48
Red Band Lights S/K	5.73	0.53	1.43	2.1
Embassy Ex Mild KS	7.8	0.70	1.24	1.31
Balmoral Lights KS	8.09	0.64	1.25	1.53
Superkings Lights	8.29	0.82	1.28	1.49
Benson & Hedges KS	10.66	0.85	1.23	1.31
Rothmans KS	11.02	0.95	1.33	1.45
Marlboro KS	12.01	0.86	1.20	1.28
Raffles 100's	12.36	1.10	1.17	1.18

Again, this may be a useful metric to be used as part of the regulatory framework.

Solanesol

Solanesol is a naturally occurring component of tobacco that is deposited during smoking in the filter butt. Watson and colleagues 36 argue that measuring solanesol in filters is an exposure marker which can be collected without invasive techniques. The amount of solanesol remains stable in the filter at least four weeks after smoking. Watson and colleagues found that the amount of solanesol deposited in a filter is 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. A key drawback with this test is that smokers may puff but not inhale so the test may overestimate smoke intake 37.

Emissions in sidestream smoke

Not many countries have tested for emissions in sidestream smoke.

In 1998, British Columbia was the first to require tobacco manufacturers to disclose the levels of potentially tobacco chemicals in tobacco smoke by brand and type of designated tobacco product, for up to 44 chemicals of mainstream and sidestream smoke for both standard and modified ISO conditions (the latter only for 1998 to 2000). Health Canada also requires disclosure of levels of constituents of sidestream smoke using both standard and modified ISO conditions. The constituents measured are described further in the next section.

Uptake of toxicants by smokers and non-smokers, disease risks and consumer behaviour.

The Institute of Medicine report 6 recommended the systematic collection of biomarker data from humans both for active smoking and ETS. This is fully supported although which biomarkers should be monitored is outside the scope of this report. The IOM also suggested that some biomarkers should be used which are less specific for individual tobacco constituents in order to monitor intro of new hazards from tobacco-related PREPS (potential reduced-exposure products).

Cotinine testing over time is extremely important as it enables a quantitative measure of nicotine intake to be monitored in smokers as characteristics of tobacco products change over time.

A comprehensive monitoring and evaluation surveillance system needs to be put in place which would monitor disease risks and profiles, and the prevalence of initiation, relapse and switching behaviour.

Development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide

Regulating cigarette smoke toxins and carcinogens

As previously mentioned, tar is not a homogeneous substance but contains thousands of different smoke constituents. Furthermore, although the particulate phase of tobacco smoke shows more overall carcinogenic activity 6, over 500 compounds have also been identified in the vapour phase. It has therefore been suggested that these constituents need to be regulated perhaps initially beginning with those specific constituents known to cause cancer or be toxic.

There are a number of issues to be considered if following such an approach:

- i. Which constituents should be regulated?
- ii. What impact might regulating one chemical have on the overall toxicity of the cigarette or tobacco?
- iii. How should the constituents be measured? As a proportion of tobacco, or cigarette smoke, or as a ratio to nicotine? How should the constituents be regulated? In whole tobacco or in the smoke?

These issues will be looked at in turn.

i. Which constituents should be regulated?

In 2000, of the over 4000 smoke constituents, 69 had been identified as carcinogens, 11 of these proven human carcinogens 13. A recent review proposed that of these, the tobacco specific nitrosamines (TSNAs) and polycyclic aromatic hydrocarbons (PAHs) were the classes of compounds which would have the biggest impact on human cancer risk but other likely carcinogens are also described below 38.

- * **Polycyclic aromatic hydrocarbons (PAHs)** are formed from the incomplete combustion of tobacco leaves. They are found in the particulate phase and are metabolically activated in humans through CYP1A1, CYP1B1 and CYP3A4 (see IOM page 375). Examples are benzo[a]pyrene (BaP), benzo[a]anthracene, benzo[b]fluoranthene, 5-methylchrsene.
- * **N-nitrosamines** include those specific to tobacco (TSNAs) and others can be formed from dietary exposures. Found in the particulate phase. TSNAs are not present in freshly harvested tobacco 39 but are formed during tobacco curing and the amount is related to the amount of nitrates in tobacco and by amounts of nicotine available. The main TSNAs thought to be carcinogenic are:
4 – (methylnitrosamino) -1-(3-pyridyl) -1- butanone (NNK), and
N-nitrosornicotine (NNN)
- * **Aromatic amines:** Aryl aromatic amines (such as 4-Aminobiphenyl, 2-toluidine, 2-naphthylamine) & Heterocyclic amines (such as 2-Amino-3-methylimidazo[4,5-[b]quinolone(IQ)). Both are found in the particulate phase. The nitrogen content of the tobacco and cigarette combustion temperature are thought to be determining factors for the yields of aromatic amines in smoke (Stabbert et al, Tob bk).

- * **Organic solvents.** Found in vapour phase. Examples: benzene, methanol, toluene, styrene
- * **Volatile organic compounds.** These are also found in the vapour phase. Examples 1,3-Butadiene, isoprene
- * **Inorganic compounds.** Found in particulate phase. Examples: arsenic, nickel, chromium, polonium-210
- * **Aldehydes.** Found in vapour phase. Examples: acetaldehyde, formaldehyde

In addition to carcinogenicity however, constituents affecting other diseases should be taken into account (see Table 6).

Table 6. Some constituents and their relationship to other diseases involved in tobacco use

Disease	Constituent(s)
Dependence	nicotine
CVD	carbon monoxide, nitrogen oxides, hydrogen cyanide
COPD	hydrogen cyanide, volatile aldehydes, nitrogen oxides, carbon monoxide

British Columbia and Health Canada required manufacturers to disclose emissions of a number of components of mainstream (and sidestream) smoke on a brand by brand basis using standard and Modified ISO tests. The constituents required are detailed in Table 7.

Concerns have been raised that regulating one specific carcinogen or group of carcinogens would not necessarily have a positive public health impact. We have already highlighted the way individual carcinogens have, to date, varied in different ways over time. The IOM report [6](#) also summarized tests showing that removal from tobacco smoke of single classes of carcinogens such as nitrosamines or PAHs, did not necessarily protect against the induction of lung tumours by smoke.

In Massachusetts [40](#), the industry voluntarily agreed to test 33 of their brands for 42 toxins in 1999 (the 'benchmarking study'). The purpose was to investigate whether the results could be used to predict the constituents in cigarette brands not tested. Independent reviewers concluded that the study could not be expected to do this.

Table 7 Constituents that are required to be disclosed for Canadian regulations

1-aminonaphthalene	Acetone	Mercury
2-aminonaphthalene	Acrolein	Nickel
3-aminobiphenyl	Propionaldehyde	Lead
4-aminobiphenyl	Crotonaldehyde	Cadmium
Benzo[a]pyrene	Methyl ethyl ketone	Chromium
Formaldehyde	Butyraldehyde	Arsenic
Acetaldehyde	Hydrogen cyanide	Selenium
Nitric Oxide	NNN	NNK
NAT	NAB	Pyridine
Quinoline	Styrene	Hydroquinone
Resorcinol	Catechol	Phenol
M+p-cresol	Tar	Nicotine
Carbon monoxide	1,3-butadiene	Isoprene
Acrylonitrile	Benzene	Toluene
Ammonia		

ii. Impact of changing individual toxins on overall toxicity

A similar benchmarking study has also been carried out in the UK, commissioned by the Department of Health and funded by the Tobacco Manufacturers Association (TMA) [41](#). This study aimed to determine the machine based yields of 44 selected constituents in mainstream cigarette smoke in a range of 25 brands having a 58% share of the UK market, although the samples were taken from a single production batch. Standard ISO tests were used. The aims of the study were to:

- to determine the yields of selected smoke constituents in mainstream smoke for the selected cigarettes, and
- to establish the functional relationships between individual mainstream smoke constituent yields and 'tar', nicotine and carbon monoxide (CO).

For most of the analytes, there was a factor of about 10 between the lowest and highest yields. There was a linear relationship between tar and carbon monoxide yields with volatile analytes having a better correlation with carbon monoxide than tar. Lower tar brands had lower yields for virtually all the analytes although it must be noted that the measurement uncertainty increased with decreasing analyte concentration.

For some smoke constituents the yields obtained from a small number of brands deviated from that expected in the linear relationships. One example is NNN which for one brand was seven times higher than any other brand. The authors surmised this was due to the use of dark air cured tobacco. Mono hydroxyl phenols also had a poor correlation with tar. Ammonia also did not correlate well with tar.

A Canadian benchmark study [42](#) was carried out to predict the concentration of 39 chemicals in tobacco smoke using the concentration of tar. This study found that the benchmark was predictive when similar cigarettes were tested ie those using the same blends of tobacco, the

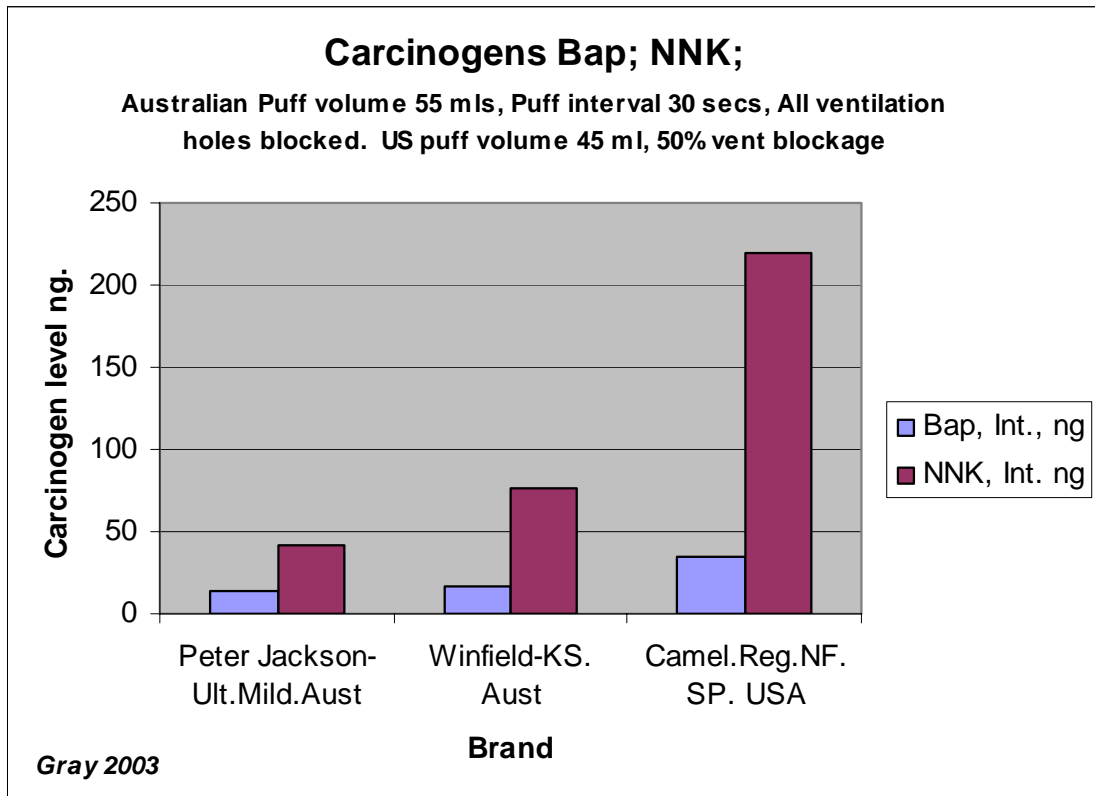
same filter material and the same papers and additive. Brands which were different did not fall within the set of predictive equations.

The results of these studies are inconclusive and further research is needed in this area. There is evidence that brands need to have similar physical and chemical characteristics if relationships between constituents and tar are to be found. The UK study showed that certain constituents do not vary in line with tar and so it makes sense to continue to measure and monitor some of the known carcinogenic constituents, particularly as this study and others before it had established that there is a wide range of the concentration of these constituents in cigarettes around the world.

For example, Gray and colleagues demonstrated international variability in constituents across the same brands used in different countries. They tested three global brands (Camel, Lucky Strike and Marlboro) for consistency of tar and nicotine yields and for two tobacco specific nitrosamines (TSNAs) [43](#). Nitrosamine levels varied between and within these three major international brands, varying from three-fold within Camel to nine-fold within Marlboro for a single nitrosamine, NNK.

A further example of variation in BaP and NNK when tested using machines with more intensive smoking parameters in selected Australian and US brands is shown in Figure 5.

Figure 5:



iii. How should the toxins be measured and regulated?

In 1998 Gray and colleagues [44](#), proposed that the constituents of cigarette smoke be regulated by establishing upper limits for known carcinogens or toxins. They subsequently proposed that the upper limits could apply either to emissions or constituents of tobacco [45](#). They suggested that existing brands could be tested for a selection of known carcinogenic substances and for those substances with substantial variability, the median concentrations could be established as a target for all brands to conform to within a certain period of time. They demonstrated this using a selection of Polish cigarette brands. Given that some products already conformed to these limits they argued that such upper limits were achievable. This proposal has been supported by WHO SACTOB [21](#) although it was acknowledged that this did not in any way imply an acceptable level of safety for any tobacco product and its emissions.

Subsequently they applied their principle of medians to data available for 34 substances tested in 25 different brands of US cigarette as part of a benchmark study performed for the Massachusetts Department of Public Health by the tobacco industry [46](#). Significant variations were observed in the levels of the toxins, for example, BaP varied seven-fold, NNK four-fold, ammonia nine-fold. They argued that if the medians were set for these 25 brands for the 34 substances tested, only one brand would remain unscathed. Gray and Boyle [47](#) also found, similar to Hoffman, that tar correlated well with some carcinogens such as PaHs, it did not correlate well with nitrosamines, reinforcing the need to regulate specific constituents other than 'tar'.

Given measurement techniques and data exist for tobacco smoke in the UK (and in Canada) the median values could quickly be set as a limit or standard for many constituents in tobacco products here. The difficulties with interpretation of the machine test still remain although Health Canada and British Columbia utilized both standard and intense machine testing regimes and this could be also considered when setting median values.

An alternative or additional form of regulation would be to measure some constituents per mg of tobacco in the cigarette. This avoids the problem of trying to emulate smokers' behaviour but is also problematic as compounds are transformed from tobacco to smoke either by direct transfer, or by generation of new compounds from pyrolysis. Ashley and colleagues [48](#) recently tested nitrosamines per mg tobacco from US brand and non US brand cigarettes and demonstrated considerable variation in TSNA levels from country to country with frequently higher levels in Marlboros than non US brands.

To our knowledge, whilst standards exist for measuring the different tobacco and smoke constituents, no limits have yet been put in place for tobacco product constituents other than through machine tests of tar and nicotine. The only standard currently set appears to be the Gothiatek standard developed by Swedish Match for snus, a form of smokeless tobacco. The Gothiatek standard sets requirements for the raw materials used in the manufacturing of Swedish snus, the manufacturing process, limits for toxic compounds (see Table 8) and product information to the consumer. All of the constituents included in the Gothiatek standard, except for pesticide residues, are included in the Canadian regulations for smoke not whole tobacco (which specified reporting requirements but did not set limits).

Table 8. The Gothiatek Standard [49](#)

Component	Limit	Component	Limit
Nitrite	3.5 mg/kg	Cadmium	0.5 mg/kg
TSNA	5 mg/kg	Lead	1.0 mg/kg
NDMA	5 microgram/kg	Arsenic	0.25 mg/kg

BaP	10 microgram/kg	Nickel	2.25 mg/kg
Pesticides	According to the Swedish Match pesticide policy	Chromium	1.5 mg/kg

mg/kg = thousandth gram per kilogram product (based on Snus with 50% water content)
microgram/kg = millionth gram per kilogram product (based on Snus with 50% water content)

There is no reason why this standard could not be applied to all tobacco whether for cigarettes or smokeless tobacco. Given that some compounds (eg PaH) are produced in the burning process however, such a standard would need to be accompanied by other standards such as setting medians for smoke constituents, or setting limits for the ratio of constituents to nicotine in the smoke. Given the fundamental role of nicotine in smoking behaviour, it would make sense to link the metric with nicotine. Nevertheless any such smoking protocol would not mimic actual smoking behaviour as described earlier in this report.

If such limits for constituents were set they should be made mandatory and manufacturers should not be allowed to communicate the changes to the consumer because they are unlikely to have major health benefits and in order to avoid repeating the low tar mistake by allowing smokers to be reassured that it is safe to carry on smoking. Communication to consumers is discussed further in a later section of this report.

Recommendations

- An array of assessments across a number of dimensions are needed to regulate tobacco products. The complexity of these regulations requires much greater regulatory capacity for tobacco product regulation than is available currently
- A proper regulatory framework needs to be established monitoring a number of different aspects of the cigarette including physical and chemical characteristics, emissions (to smokers and non-smokers), human exposure, biomarkers etc. Regulators are obliged to monitor physical and chemical characteristics of tobacco products over time
- All new products should be fully characterised and before entry to the market the manufacturers should demonstrate that they have real potential to significantly reduce the harmfulness of the product
- Suggestions that have been made to adapt the FTC/ISO tests to more closely approximate smoking behaviour still will suffer from the fact that no single puffing regime will reflect how smokers behave. Nevertheless, capped ratios of individual carcinogens to nicotine using modified and standard ISO test regimes may still be useful metrics to monitor as part of the regulatory framework
- Setting current median levels of constituents as maximum levels per mg of tobacco and possibly as a proportion of whole smoke should also be given serious consideration

Development of standards concerning products other than cigarettes, in particular hand rolling tobacco

In the UK, over a fifth of smokers (22%) now smoke hand-rolled cigarettes compared to 10% in 1984. Hand-rolled smokers are predominantly male and found in more deprived groups in society. Customs & Excise estimate 69% 50 of hand rolling tobacco avoids UK taxes (51% through smuggling and 18% through cross-channel shopping) and therefore may become more popular in the future. The proportion of smuggled handrolling tobacco has decreased from 63% since 2000/01.

Hand-rolled cigarettes do not need to comply with the tar, nicotine and CO machine based maximum yields. The Department of Health commissioned Arista Labs to examine the machine based deliveries of five blends of hand-rolling tobacco which cover 97% of the UK market 51. Even though they used standardized 'fine cut smoking articles' with 5.2mm tubes and 400mg tobacco, they found that within each brand of hand-rolled tobacco considerably more variation than was found within brands of machine manufactured cigarettes. The nicotine yields were between 0.79 and 1.27 mg/cigarette and the tar values 11.7 to 14.3 mg / cigarette.

Hand-rolled tobacco products need to be regulated but it is unclear how best this can be done as the smoker makes the product according to their needs and can alter the amount of tobacco that they use easily. It is important that regulators require full characterization and disclosure of the products and setting standards for carcinogens and toxins per mg of tobacco would appear to be the only meaningful regulatory measure that could be used.

Recommendations:

- A tobacco products regulatory framework needs to take account of the growing use of hand rolling tobacco in the UK
- Hand rolling tobacco does not lend itself easily to regulation
- Regulators should require full characterisation and disclosure of hand rolling tobacco products from manufacturers
- Setting standards and toxins per mg of tobacco or per mg of tar would appear to be the only meaningful regulatory measure that could be used for hand rolling tobacco products

4. Ingredients

The EU legislation on ingredients

Article 6 of the Directive 2001/37/EC stipulated that Member States required 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 should be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products and indicate their function and category. The list should 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 required information had to be provided on a yearly basis and for the first time by 31 December 2002 at the latest. The information had to be disseminated by appropriate means but the requirement to do so was qualified by reference to trade secrecy, although it then seems to be up to individual Member States to decide how much of this information they make public. All Member States had to ensure however that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields was made public.

On the basis of the information required from the industry and transmitted to the Member States, the Commission should submit a proposal by 31 December 2004 providing for a common list of ingredients authorised for tobacco products, taking into account inter alia their addictiveness.”

UK regulations

The UK regulations specified that the toxicological data concerning the ingredients of the tobacco product

- (i) in the case of products intended to be burnt, burnt and unburnt
- (ii) in the case of products not intended to be burnt, unburnt
which should for each ingredient
- (iii) refer in particular to their effects on health
- (iv) include any effects produced in combination with any of the other ingredients of that
product that are not produced by that ingredient alone, and
- (v) take into account any addictive effects

There appear to be no obligation on the Department to make this information public (although they are likely to do so).

The reaction of the tobacco industry

The industry is not complying with the Directive and is not providing the Member States with “a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.” Companies such as Philip Morris provide information to EU governments according to the three model list (see www.pmintl.com)

The information comes in three parts:

1. Composite list of ingredients added to tobacco

This list does not contain all ingredients added to tobacco by brand and per type, but the list of ingredients for all cigarettes and roll your own tobacco brands manufactured by the tobacco company in a specific country.

For each ingredient the list contains:

- name of the ingredient in alphabetical order;
- function of the ingredient;
- "quantity not exceeded" (calculated from the highest level of use in a single brand and expressed as a percentage of the tobacco weight);
- examples of other consumer products in which the ingredient is used or occurs naturally.

2. Composite list of ingredients present in non-tobacco components

The ingredients present in non-tobacco components are listed by category in descending order by weight. For each ingredient, the list includes the "quantity not exceeded" (calculated from the highest level of use in a single brand and expressed as a percentage of the total weight of the cigarette).

3. By-brand disclosure

The tobacco ingredients by-brand list includes ingredients used at levels greater than 0.1% of the weight of the tobacco rod (the column of tobacco in each cigarette). In this list, the flavours that make up each brand's unique flavour characteristics are grouped under "natural and artificial flavours". By-brand processing aids and preservatives added to the tobacco, which are not significantly present in, and do not functionally affect, the finished product are also not disclosed in this list. Ingredients in the by-brand list appear in descending order by weight.

Dutch legislation (14 April 2003) requires that companies provide a list A with all ingredients in a given brand and type of product (indication of the exact quantities being optional) which would be made public. In addition, the companies must provide a list B with all ingredients in a given brand and type of tobacco product, which does indicate the exact quantities. List B will not be made public but was to be forwarded to the Commission. Tobacco companies such as Philip Morris, BAT, JTI and Gallaher have challenged the Dutch ingredient legislation. In a Philip Morris press release on 28 August 2003, Senior Vice President Corporate Affairs David Davies commented:

"The dispute in the Netherlands is not about providing ingredients information - we have already done that, in full compliance with EU requirements" and added "This is about protecting our trademarks against a government's determination to publicize the precise brand recipes for all tobacco products, a policy that serves no public health goal and provides no consumer information"

According to Philip Morris:

"the Dutch Government's requirements would make specific brand recipes available to competitors and counterfeiters and goes far beyond the EU Directive which establishes a community wide standard for providing information on ingredients in tobacco products. The EU Product Directive guarantees that specific brand recipes which constitute trade secrets are protected."

Tobacco companies argue that the public list A is too detailed for the consumer and that the Dutch authorities do not provide enough guarantees that the confidential list B will not be leaked to outsiders. Ingredients disclosure remains a very sensitive question for tobacco companies. In the past they challenged the Massachusetts legislation on ingredients with arguments on the protection of trade secrecy. After 5 years of legal battle, the outcome in 2002 was successful for the tobacco companies and the Massachusetts legislation on ingredients has been abandoned. However tobacco companies have also challenged the legislation in Canada and British Colombia, where they lost their legal battle. On the website of British Colombia, one can access the data on ingredients for each brand. www.healthplanning.gov.bc.ca/ttdr/index.html .

The information on the B.C. website is similar to the list A of the Dutch legislation. The claim of the industry that the Dutch A list (all ingredients without the quantities) will provide the counterfeiters and competitors information of highly confidential nature is ridiculous as the information can be accessed on the website of British Colombia. Although Canadian tobacco companies have acknowledged publicly that they use very few additives in their tobacco products, the disclosure applies to all cigarettes on the market.

The weakness of the European legislation on ingredients

Wayne of the Massachusetts tobacco control program summarized what is already known about additives ⁵²:

- The modern U.S. style cigarette contains about 10 percent additives by weight
- Potentially hundreds of additives are commonly used (599 list; industry websites)
- Most additives are used in very small amounts—less than .01% of total weight
- Relatively small group of additives used at “high” levels (sugars, humectants, ammonia compounds, cocoa, licorice, menthol)

And

- Lack of knowledge is a huge barrier
- Impact of pyrolysis products and synergistic effects make evaluation of toxicity of individual components nearly impossible
- **Effects on behavior and uptake may be more significant than measured toxicity of any individual compound**

In 1997 the Commission Services wrote to all Member States regarding their policy on additives in cigarettes. The analysis of the replies indicates that there is a wide variety in the rules on additives between the Member States. Directive 2001/37/EC could therefore be considered as a first step forward, but it contains many weaknesses. The industry is not providing the necessary information on ingredients as required by the Directive. As result of the legal action by the tobacco companies against the Dutch legislation, the implementation of the Directive on ingredients is likely to be postponed. It is for instance very unlikely that the Commission will come up with a common list of EU agreed ingredients by the end of the year 2004.

However, even if the industry had been more cooperative, Article 6 of the Directive itself contains many weaknesses.

Toxicological data available to the manufacturer

Article 6 stipulates “*The list (of ingredients) 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*”.

There is no obligation for the companies to provide data on toxicology or addictiveness, only the *available information*. Which information will be transmitted? Which methods for measurement

will be used? Are data provided for all ingredients, flavorings and processing aids? Are data presented for each ingredient or for all ingredients in the cigarette, taken into account the synergetic effect? Are the data reliable? Are the data comparable? Do Member States have the competence to examine, check and control the data provided by the industry? Are there enough independent laboratories to examine the industry data? Do the independent laboratories use the same methodology?

It is very likely that the tobacco industry transmitted information on toxicology to the Member States will be unsatisfactory and insufficient to compare the data based on international accepted test methods.

Inadequate information on addictiveness

The information on addictiveness is even more likely to be unsatisfactory as the official position of the industry has always been that they never add ingredients which enhance addictiveness. Tobacco companies are not required to provide data on essential information to measure the addictiveness of the total "nicotine" impact of the cigarette such as the pH of cigarette smoke (except in Canada) and the proportion of free nicotine. As stated above, the interaction between additives or constituents and free nicotine are complex, but need to be fully investigated.

The Directive defines ingredient as:

"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."

Ingredients are those substances which have been added during the manufacturing process, but not from the agricultural practices. This is a serious limitation. The best example to illustrate this again is ammonia. In the list of ingredients provided by Philip Morris to the Member States ammonia is not mentioned. The claim that PM does not add ammonia as an ingredient does not mean that ammonia is not present in the product. Tests of the French consumer organisation Institut National de la Consommation indicated that ammonia was highly present in cigarette brands sold in France in 2001. The tests could not indicate whether ammonia was added during the agricultural or manufacturing process 53. Jeffrey Wigand confirmed during his presentation in Bilthoven that ammonia is still present in the cigarette brands sold in Germany. Wigand announced that he will make these results public in the coming months.

In the 2000 Tobacco Encyclopaedia of Tobacco Journal International, ammonia is described as playing an important role in the metabolism of the tobacco plant.

"It is added as its ammonium salt to growing plants and present in farmyard manure. Ammonia is released in the first days of the curing, while in fermentation large amounts of nitrogen escape in the form of gaseous ammonia, thereby giving rise to the characteristic smell of well-fermented tobacco 54."

Hence it is not surprising that the companies can claim not to add ammonia as an ingredient, as it is already present in the tobacco leaf. The WHO scientific committee on tobacco product regulation (SACTOB) 21 has a better definition of ingredients and defined them in the following way:

"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."

The advantage of the SACTOB definition is that also the agricultural practices are taken into account.

An argument for banning all additives

Although it is important to regulate the use of ingredients in tobacco products, the toxicity of most additives would be considerably less than the toxins in tobacco smoke. However, if the additive acts in such a way as to increase smoking, this could cause much greater overall harm.

Given that most additives are there to improve the attractiveness or palatability of cigarettes, they are likely to be increasing tobacco-related harm. It is arguable therefore that all existing and new additives should meet a test of public health or public interest (with the burden of proof resting on the industry) or be withdrawn from use.

Communication of ingredients is discussed in Section 5.

Recommendations on ingredients

- The tobacco industry is currently not complying with the requirements of the directive concerning ingredient disclosure
- The current directive can be improved in several ways, for example in how ingredients are defined
- The toxicity of most additives is considerably less than the toxins in tobacco smoke and hence regulations around additives are unlikely to make a significant impact on public health
- There is a compelling case for banning all additives unless they meet a test of public health or public interest with the burden of proof being on the industry

5. Evaluation of tobacco products which may have the potential to reduce harm

Article 11 specified the need for the review to consider the evaluation of tobacco products which may have the potential to reduce harm. There are a wide range of these products currently available ranging from reduced TSNA cigarettes to heated tobacco to smokeless tobacco products with many more devices in development. It is only a matter of time before some of these products are marketed in Europe yet there is currently no regulatory framework within which these products could be meaningfully assessed. This section also examines the role of medicinal nicotine products which we believe need to be taken into account, although they are outside the remit of the EU directive.

A hierarchy of harm

Warner (2003 [55](#) see Table 8) categorized products according to their relative harms. He drew up three categories of products – the least harmful medicinal nicotine products, moderately harmful smokeless tobacco products and then the most harmful products which included modified cigarettes.

Table 9 Hierarchy of harm reduction techniques, most to least desirable
Source: Warner, 2003.

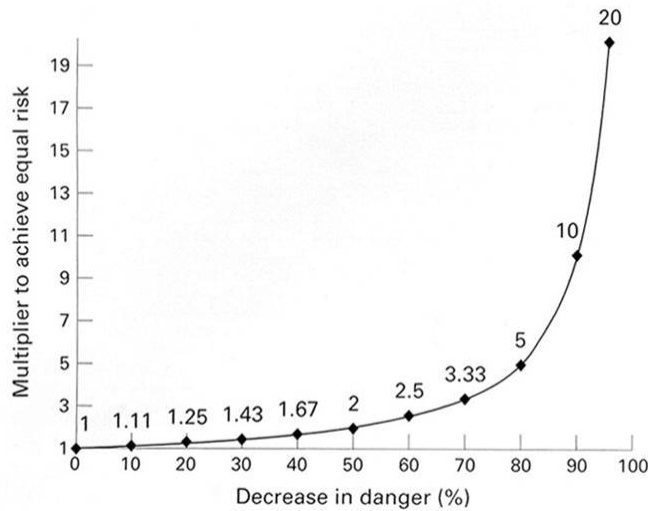
- Avoidance of initiation (prevention)
- Complete cessation

- Substitution of least harmful alternatives (e.g., medicinal nicotine)
- Substitution of moderately harmful alternatives (e.g., smokeless tobacco)
- Substitution of most harmful alternatives (e.g., modified cigarettes; reduced smoking)

Individual versus population health effects

Kozlowski and colleagues [56](#) developed the concept of a risk use equilibrium that demonstrated that if use of a product rose higher than risk compared to cigarettes decreased, there would be a net negative impact on public health. If use rose lower than the risk decreased then there would be a net positive impact on public health. He demonstrated this graphically (Figure 6). The graph shows the equilibrium ie no change in population level risks.

Figure 6 – From Kozlowski 56, in Tobacco Control.



The risk use equilibrium demonstrated that medicinal nicotine is the best harm reduction strategy for current smokers after abstinence. Some forms of smokeless tobacco have subsequently been added to this by Kozlowski 57.

The equilibrium also demonstrated that any combusted tobacco product will constitute a very poor prospect for harm reduction as at a population level it would be likely to increase harm. This reiterates the point made in the previous section that attempts to reduce the harmfulness of cigarettes will be unlikely to have a significant impact on public health. Clearly non-combustible products offer the most promise of harm reduction and within this category are medicinal nicotine and smokeless tobacco products. These are discussed further below.

Medicinal nicotine products

Medicinal or therapeutic nicotine products (currently nicotine replacement therapies, NRT) are outside of the remit this directive but we believe that there should be a common regulatory framework for all nicotine and tobacco products if significant progress is to be made towards reducing the dominance of the dirty nicotine delivery systems over the next ten years.

Medicinal nicotine delivery devices are licensed for the relief of withdrawal from nicotine when abstaining from cigarettes as an aid to smoking cessation. As mentioned above NRT products are much less harmful than cigarettes, which are very 'dirty' delivery systems for nicotine.

In all countries NRT products are regulated within the country's medicines regulatory framework. In the UK, the Medicines and Healthcare products Regulatory Agency regulates NRT products under the Medicines Act. As a result their abuse and dependence potential are minimised. Similarly, the packaging of current therapeutic nicotine products is in sharp contrast to the attractive marketing associated with cigarettes. In addition, there are a number of constraints on NRT use. These constraints are drawn up by regulators who have responsibility for the licensing of pharmaceuticals and focus on the potential harm caused by the NRT product without having any responsibility for the consequences of continued or additional smoking which might arise when the NRT is not used.

Immediate steps should therefore be taken to relax the constraints around NRT use including [58](#):

- Access – although some NRT products are on general sale, their sale is still restricted to a few main supermarket chains, and even these products are not as accessible as cigarettes and other tobacco products which are available in corner shops, petrol stations etc.
- Use by restricted groups – NRT products currently contain warnings about their use with some population groups eg young smokers, pregnant smokers, smokers with cardiovascular risk. Whilst some of the restrictions have been relaxed in recent years, the likelihood of smokers continuing to smoke and the greater risks to health this implies needs to be taken into consideration and such warnings need therefore to be put in the context of the dangers of continued smoking.
- Packaging, product design and pricing – these aspects are strictly regulated and as a result these products are far less attractive than cigarettes and other tobacco products. More research is urgently needed to explore price elasticity and marketing elasticity in relation to NRT products in order to make them more accessible to consumers than cigarettes.
- Use for temporary abstinence and nicotine maintenance – consideration needs to be given to lifting the restrictions on how these products can be used if they are to compete with cigarettes (see below).

In the UK there are currently six different forms of nicotine delivery – gum, patch, nasal spray, inhalator, sublingual tablet and lozenge. The nicotine dose and speed of nicotine delivery differ between the products with the nasal spray being the fastest speed of delivery with nicotine peaking 10 minutes after a dose of spray and the patch the slowest with nicotine peaking after 4-9 hours of putting the patch on. These can be compared with cigarettes where a concentrated bolus of nicotine reaches the brain within 10 seconds of a puff.

Whilst steps can be taken to increase the accessibility of NRTs (such as enabling their use for temporary abstinence and making them more widely available), the current NRT products clearly cannot compete with cigarettes in terms of satisfaction and speed of nicotine delivery. If a pharmaceutical company created such a device it is likely that medicines regulators would refuse it a license on the grounds of its higher dependence potential and abuse liability. Hence the medicines regulatory framework ensures that new non-tobacco nicotine products, which could compete directly with tobacco, are unlikely to be developed and marketed widely and effectively guarantee the market for recreational nicotine to the most harmful nicotine delivery system, the cigarette.

In 1991 Professor Michael Russell argued the need for cleaner nicotine delivery systems, yet still 13 years later, no alternative competitive form of clean nicotine delivery systems exists. More experts [59](#) are now agreeing that:

'a new and better range of addictive recreational nicotine is needed'.

It is likely that it will only be really possible for competitive recreational nicotine delivery devices to be produced if there is a single regulatory framework encompassing the range of clean and dirty nicotine delivery systems in which regulators would need to take into account the death and disease caused by cigarettes if smokers did not use the nicotine delivery devices. . It is possible that this could happen with different regulators managing the different devices but information would then need to be shared between the regulatory bodies.

Smokeless tobacco products

Smokeless tobacco comes in two main forms: snuff and chewing tobacco. Snuff has a finer consistency and is marketed in both dry (oral and nasal) and moist (oral only) forms, sometimes in sachets (like tea-bags). Chewing tobacco comes in the form of loose leaf (in pouches of tobacco leaves), 'plug' or 'twist' form. The tobacco can also be mixed with other psychoactive ingredients.

Article 8 of the Directive bans the placing on the market of 'tobacco for oral use', defined as '*all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product*'. Hence in the EU apart from Sweden which had a derogation because a type of moist snuff (snus) was already commonly used, chewing tobacco and of course cigarettes are allowed, whereas snuff is banned.

Smokeless tobacco use is prevalent in some countries in particular, many Asian and some African countries. It also used to be common in the United States until at the beginning of the last century people became aware that it could spread diseases like tuberculosis (because of the need to spit). As mass produced cigarettes became available, smokeless tobacco use therefore declined, becoming confined to some parts of Scandinavia and some American states.

However, the tobacco industry continued to explore the potential of other tobacco products. In the 70s and 80s some forms of smokeless tobacco teabags became popular again in the US largely with teenage boys. The manufacturer of these products, US Tobacco, planned to manufacture these products in Scotland but negative publicity by tobacco control advocates caused first the announcement of a voluntary agreement restricting promotion of the product, followed by an announcement that the British government would ban oral snuff under consumer protection legislation. Following an appeal by US Tobacco the ban was overturned but EU legislation introduced a ban across the whole of the EU with a derogation for Sweden where its use was more widespread. The ban hinged on evidence of carcinogenicity of oral snuff products (eg [60](#)) together with the desire to ban new tobacco products before they became established in markets. In addition, there was a concern that US Tobacco was specifically targeting youth with its marketing of smokeless products.

Recently, the ban on smokeless tobacco in Europe has been the subject of much debate. More recent evidence has indicated that some forms of smokeless tobacco (such as the Swedish snus which is manufactured according to the Gothiatek standard described above) are one or two orders of magnitude less harmful than cigarette smoking (eg [61](#)). Hence, whilst the ban was based on key reviews of the evidence at that time, the more recent evidence indicates that the differences in health risks between smokeless and cigarettes may be 'significant'. Hence the ban in Europe leaves the tobacco market dominated by the most deadly form of nicotine delivery system, the cigarette, and nicotine users are not permitted to access and use a much less dangerous product, snus.

Those against the ban being lifted raise concerns that the introduction of other forms of tobacco or products, which may be less dangerous, might result in a net negative public health impact as the tobacco industry would exploit such a move, in a way similar to their exploitation of the low tar cigarettes, meaning that the products could encourage:

- More young people to use tobacco or to smoke
- More ex-smokers to use tobacco again or relapse to smoking
- Smokers who might have quit if the products hadn't been available to switch to use the new nicotine product instead
- And sustain ongoing use of conventional tobacco products

Some also argue that whilst Sweden has the lowest tobacco related mortality and morbidity figures across Europe, this may not be replicated across other cultures if smokeless tobacco use was encouraged.

Whilst there is an argument that consumers have a right to be able to access and be aware of products offering any reduction in harm [62](#), the impact on population health needs to be taken into account. Kozlowski and colleagues endeavoured to do this with the risk-use equilibrium described above, which demonstrated that if some forms of smokeless tobacco are orders of magnitude less harmful than cigarettes then no increase in use could outweigh the public health benefits of allowing them on the market.

The effect of smokeless tobacco on smoking and public health are discussed in much greater detail elsewhere [61](#). Bates and colleagues [63](#) proposed that the ban on some forms of smokeless tobacco be replaced with an evidence based regulatory framework within which standards would be set for maximum levels of carcinogens and other toxins for smokeless (and smoked) tobacco products. Such a framework would focus on eliminating products that are the most harmful to health. Detractors agree that if there is a role for oral tobacco then this must be overseen by a comprehensive regulatory authority [64](#).

It has been argued that it would be better to make medicinal nicotine products more widely accessible and encourage more tobacco competitive recreational clean nicotine products without removing the ban on smokeless tobacco. Immediate steps can and should be taken to provide incentives to pharmaceutical manufacturers to bring to market such clean nicotine products and broaden access to existing NRT products. However, in the absence of such clean nicotine products removing the ban on smokeless tobacco within an evidence based framework would give smokers an immediate option to reduce the harm. There is also an argument for allowing a range of harm reduction products on the market to enable consumers to have a choice as to which products they find most acceptable to them. Tobacco manufacturers could also be encouraged or indeed compelled to replace their cigarette products with non-combustible tightly regulated products over time. With the advent of clean recreational nicotine products, a range of regulatory controls such as differential tax and access can be brought into play to make the clean nicotine products more attractive than the non-combustible tobacco products which could be made more attractive than cigarettes to consumers [65](#).

If regulators are to make a serious attempt to shift the market in favour of less harmful nicotine products in the immediate future, then it is hard to imagine a sensible nicotine regulatory framework in which smokeless tobacco products do not play a role. Unless the ban is reversed attempts at harm reduction will, in the short term, be largely confined to tinkering with the cigarette which is so deadly, that this would have minimal impact on morbidity and mortality. Immediate action should be taken however to redress the misunderstandings about the role and risks of nicotine in tobacco use.

Recommendations on potential less harmful products

- All tobacco and nicotine products should be evaluated within a single regulatory framework in order to shift the nicotine market in favour of cleaner forms of nicotine delivery over the next few decades
- Regulators controlling therapeutic nicotine products need to take account of what happens if these products are not used
- The most promising harm reducing products are non-combustible nicotine delivery systems. Currently this includes NRT and some forms of smokeless tobacco

- Immediate steps should be taken to correct the widespread misunderstandings about the role of nicotine and the risks of NRT and broaden their access in terms of lifting restrictions on their use for some population groups, lifting restrictions on uses other than cessation, and enabling the purchase of NRT through a wider variety of retail outlets
- Steps should be taken to incentivise the production of clean recreational nicotine delivery systems
- If the ban on smokeless tobacco is removed, this should only be done within an evidence based regulatory framework which sets standards for carcinogens and other toxins for all forms of tobacco

6 Consumer information

Article 5

This article laid out the requirements for the display, positioning and size of the tar, nicotine and carbon monoxide yields of cigarettes and the content, positioning and size of health warnings on cigarette packs and tobacco for oral use (where different warnings were to be used).

On 5 September 2003, the Commission provided the rules on the use of colour photographs or other illustrations as health warnings on tobacco packages although a library of pre-rested source documents for use will not be provided by the Commission until 30 September 2004 and the earliest these could be applied would be from 1 October 2004. Member States could choose whether they required the additional warnings with colour photographs/illustrations.

Article 5 also set out the need for tobacco products to be marked in any appropriate manner, to ensure product information and traceability for the purposes of monitoring compliance with the Directive. The directive indicated that the technical measures to apply to this provision should be adopted in accordance with procedures laid down in Article 10(2) which referred to Council Decision (1999/468/EC) laying down procedures for the exercise of implementing powers conferred on the Commission. The UK regulations indicated that a producer of a tobacco product should ensure that each packet of that product carried a code marking, whether by batch number or otherwise, whereby the place, date, and in the case of a product other than cigars, the time of its manufacture could be determined.

Communication to consumers has failed

Information on constituents and yields

The directive obliges the printing of the tar, nicotine and carbon monoxide yields of cigarettes on the packs. The provision has been strongly criticized as the tar and nicotine yields are based on ISO measurements and do not provide meaningful information for the consumers as discussed above. One of the recommendations from the WHO conference "*Advancing knowledge on regulating tobacco products*" held in Oslo, 9-11 February 2000, was to remove these yields from the packs.

While a consensus has been growing that the ISO tar and nicotine yields should be removed, there is less consensus on what should replace them. Consumer research around the world indicates a great deal of misunderstanding about tobacco constituents.

Research in England in 1998 showed that smokers were aware of the presence of tar and nicotine, but were less certain about the function of these substances and their associated health risks [66](#). A survey in 2001 in Belgium found that 50% of the smokers believed that nicotine was the most dangerous substance in the cigarette whereas 44% mentioned tar [67](#). These results stressed the need to inform smokers better on the exact role of nicotine and tar. Similar misunderstandings have been found among smokers in Canada. When Canadian adults were asked in 2001, if they could name any chemicals or toxic substances in cigarettes or cigarette smoke, 73 percent mentioned nicotine. A majority also mentioned tar (53%), 14% mentioned carbon monoxide and 25 percent some other substance (including 4% arsenic, 2% benzene, 2% ammonia) [68](#).

Qualitative research in Australia in 2000 has shown that most smokers freely admitted that the technical terminology used was meaningless (e.g. "No too complicated, what the hell is hydrogen

cyanide?" Female 15-17 years) and even when such contents are made known to them they cannot easily determine the potential harm 69.

Hastings and colleagues 70 conducted qualitative research across Europe (Finland, France, Germany, Greece, Spain, Sweden and the UK) with smokers and demonstrated that the tar, nicotine and carbon monoxide yields are virtually meaningless to smokers. They commented that

'Only the tar yield meant much to smokers, but even then most ignored it For those who did consider it, some – typically new smokers, or established smokers trying an unfamiliar brand – used it to select a brand they might like, while a small minority used it to find what they perceived to be 'healthier' low tar products.'

The nicotine and carbon monoxide yields meant even less to smokers who thought they probably related to health consequences. Hastings suggested that making the information more prominent would not ease communication problems. They suggested explanatory text providing information on these constituents, although they acknowledged that this would probably present considerable challenges.

There is very little research available to guide what information would be most useful to smokers. Sweanor recently proposed that to enable smokers to be 'fully informed', information concerning susceptibility to and prognosis of the various diseases, how to reduce risk and steps to reduce risk, needed to be communicated. However, he cautioned that given most smoking starts in childhood and that cigarette smoking is extremely addictive, can be rapid, freedom to act in the face of information can be severely compromised 65.

What follows are details of some methods that have been tried to improve consumer information in this area. However, more research is needed before any decisions concerning the optimum forms of consumer information are taken. It will be important to clarify what the end goal of such information is. Rather than simply informing consumers, like Sweanor, we believe it should be aimed at encouraging and facilitating smokers to successfully reduce their risks and quit smoking.

Printing ranges of yields

In Canada, a range of yields is published on cigarette packs. This is based on the premise that approximately 95% of smokers are expected to have a mouth level exposure of somewhere between the ISO number and the Canadian 'intense' ISO standard and hence both yields are put on packages (see Figure 7).

It is not known how consumers respond to this information but it is extremely doubtful whether this will be any more meaningful than the yields and hence this approach is not recommended here.

Figure 7 – Canadian consumer information based on standard and modified ISO test methods

	Emission Levels	
	Previous	Current
Tar	8 mg	8-29 mg
Nicotine	1 mg	1-2.6 mg
Carbon Monoxide	9 mg	9-27 mg
Formaldehyde	n/a	0.035-0.13 mg
Hydrogen Cyanide	n/a	0.073-0.25 mg
Benzene	n/a	0.034-0.08 mg

Emission levels for an extra light, regular filter cigarette.

* Providing a low and high range for emission levels of these toxic chemicals is reflective of how people smoke differently and provides a more accurate indication of the real health risks to individuals exposed to tobacco smoke. The best way to reduce the potential health risks associated with these toxic chemicals is to quit!

Package inserts

More information on constituents and ingredients can be provided on the packs, but there is probably not enough space to explain these in an understandable way to consumers. Another way to inform smokers could be through the use of pack inserts. Canada has made health messages on either the pack or on pack inserts obligatory 71. Packages with an inner slide put the information on the slide but this is only the case for packs of 25 cigarettes (the dominant pack size in Canada), packs of 20 cigarettes do not have the slide and then must have package inserts.

Research in 2000 indicated that although 93% of a sample of smokers noticed the insert only 68% took it out. More respondents thought that information on the flip or slide of the pack rather than a package insert would be more effective. The authorities were perhaps not convinced of the value of inserts as these were to be limited to highlighted text without full colour, pictures or graphics.

Philip Morris (PM), on a voluntary basis, introduced pack inserts for their products in several European countries at the end of 2003. One difference between the Canadian and the PM leaflets is that the PM packs can be opened without noticing the leaflet, which is on the outside of the pack. The Canadian leaflets are on the inside and are at least noticed when the pack is opened. The design of the PM leaflets is such that it would be surprising that smokers would read them: for example they are too long, have no proper layout, no colour, no alternation of the messages and generally a boring content.

One advantage of the inserts is that they could be made to look comparable to the information provided in inserts for therapeutic nicotine products and could therefore allow some consistency across the range of nicotine delivery products. The costs of the inserts should be borne by the manufacturers.

The use of websites

A third possibility is the use of websites. The authorities in British Columbia inform the public on ingredients on their website, which receives an average of 1000 visitors a month 72. This technique has been used in a recent television advertising campaign on the deceit caused by low tar cigarettes by Cancer Research UK which gave a website address for consumers requiring further information. The website received about 7.5 thousand visitors in the first month of the campaign. A more recent campaign solely using on-line advertising such as banner advertising on sites popular with the target audience received about 11 thousand visitors in the first week (Robertson K, personal communication).

The website address on ingredients could be mentioned on the packs for instance instead of the meaningless ISO tar and nicotine yields. The website approach has two advantages: space is not a problem and it can be consulted by those who are interested in the issue. However, this information could be too technical and it would only be accessed by a subset of more motivated smokers.

Recommendations:

- Tar, nicotine and CO yields need to be removed from packs
- The desired impact of consumer information should be clarified. We believe it should be aimed at encouraging and facilitating smokers to successfully reduce their risks and quit smoking
- Consumer research is needed on what information should be communicated instead and how best to do this

Health Warnings

Enhancement of health warnings

There is evidence that the new enhanced health warnings are having an impact on smokers. Emerging evidence from the UK indicates that the enhancement of the warnings substantially increased their salience, smokers thinking about warning labels, increases in reported forgoing of a cigarette because of the labels, perceived effectiveness of the warning labels, and smokers considering warning labels as a motivation to quit 73 compared with reactions to warnings in countries outside of Europe, where changes were not made.

In November 2002, Defacto presented the results of Dutch studies about the effects of the new health warnings. These studies indicated that some adult smokers said that they smoked less and were more motivated to quit by the new health warnings. They found an even stronger effect among 13-18 year olds: 28% said that they smoked less because of the new health warnings 74. Another study found that the inclusion of the quit line number on the packs had increased calls. They also found that whereas previously the quit line had helped motivated smokers from middle socioeconomic groups, with the numbers included on pack warnings, lower socioeconomic groups in particular called in 75.

Poland also introduced health warnings occupying 30% of the largest sides on cigarette packs in 1998. Research indicated that among Polish male smokers, 3% said that they had quit following the introduction of the labels, an additional 15% said that they had tried quitting and a further 14% said that they understood the health effects better because of the warnings [76](#).

Australia had introduced similar larger health warnings (top 25% of the front of the pack) and detailed health information (covering one third of the back of the pack) in 1995. Following this, one study [77](#) showed that more than a third of smokers reported being affected by the warnings, with reductions in consumption and talking about the warnings being the most salient feature. Another study [78](#) indicated that the majority of smokers (60%) believed that the warnings and health information had improved their knowledge of the health effects of tobacco, 78% believed that they had some effect on their behaviour, a third believed the labels had helped them to smoke less and 45% of recent ex-smokers believed that the warnings helped them to give up.

Pictorial health warnings

As mentioned above, EU member states have the option of introducing pictorial health warnings when the pre-tested source documents are made available later this year. Research on pictorial warnings suggests that these have been effective.

In December 2000, Canada was the first country in the world to introduce health warnings accompanied by pictures, occupying 50% of the front and back of packs. This move was accompanied by the inclusion of one of 16 health messages on the inside of the pack including more detailed health risk information or messages encouraged smokers to quit.

Research among a sample of smokers from South-Western Ontario, Canada, indicated that nearly all the smokers (91%) sampled in October/November 2001 reported having read the warning labels and demonstrated a thorough knowledge of their content. A measure of cognitive processing was devised to assess the salience of the warnings and the extent to which smokers elaborated upon their information. A strong positive relation was observed between this measure of cognitive processing and smokers' intentions to quit. The cognitive processing predicted cessation behaviour at a three month follow up in that those smokers who had read, thought about, and discussed the new labels at baseline were more likely to have quit, made a quit attempt, or reduced their smoking three months later, after adjusting for intentions to quit and smoking status at baseline [79](#).

Hastings and colleagues [70](#) also tested pictorial images in the form of some of the Canadian images in their qualitative research with smokers in Europe. They found that the pictorial images were attention grabbing and communicated the messages effectively although the authors believe that the more shocking pictures necessitated supportive messages for example, about quitting services.

Supportive messages could be communicated either through package inserts or websites as described in the previous section.

Hastings and colleagues considered the logistical problems of requiring pictorial warnings given that Canadian packs are considerably bigger than European ones and that their warnings have explanatory texts in addition to the pictures. They suggested that it may also be necessary for the Commission to introduce new legislation, further expanding the space available for messages. They also indicated that tight control of the messages and images was essential. In Brazil, where colour photographs were introduced with health messages in January 2002, slips were already being inserted into the packs for smokers to stick over the graphic images.

Hastings also pointed out the need for cultural sensitivity depending on the extent to which the country was pro-or anti-smoking. In addition they suggested that problems of acceptance and understanding of the messages, for example, around impotency could be eased with media

advocacy. Finally, they felt that smokers were feeling somewhat victimised by the new messages but that this was eased by supportive messages.

Hastings commented that any messages and warnings would need revision and refreshment if they were to remain prominent and for both pictures and text, careful pre-testing was necessary.

Recommendations:

- Pictorial health warnings should be adopted when this becomes possible later this year. These should be accompanied by messages which are supportive and facilitate quitting
- All health warnings and messages will need to be pre-tested and should be continually refreshed and revised if they are to remain impactful

Misleading brand descriptors

Article 7 banned the use of misleading product descriptions, stipulating:

'With effect from 30 September 2003, and without prejudice to Article 5(1) [concerning the display of tar, nicotine and carbon monoxide yields], texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products'

The UK regulations contained a slightly different wording:

"No person shall supply a tobacco product the packaging of which carries any name, brand name, text, trademark or pictorial or any other representation or sign which suggests that that tobacco product is less harmful to health than other tobacco products".

It specified that this did not apply where a tobacco product was or was to be supplied for consumption outside the UK.

Light descriptors were thought to be misleading in two senses. First, these labels were found on cigarettes across the full range of nominal yields of cigarettes when examining brands internationally. In 2000, brands labelled light in the UK had tar yields ranging from 5 to 11 mg tar 82. Rickert and colleagues in 1989 found light descriptors in brands with nominal tar ranging from 4mg to 14 mg 80. Ultra lights tend to have nominal tar yields of 6mg or less in the US, but around 1 mg in the UK.

More importantly however, several studies had shown that smokers see these terms not as technical descriptors but as implying health benefits. Giovino and colleagues in the US found that smokers of low tar cigarettes and smokers who had switched to these brands were more likely, than high tar smokers or never switchers, to acknowledge the dangers of smoking, say that their health had been affected, be concerned about health effects and believe that their cigarettes were safer 81. Kozlowski and colleagues found that 58% of ultra light and 39% of light smokers said that a reason they smoked those brands was to reduce the risks of smoking 82. Research in the UK also found that a main reason to switching to a light brand was concern about health, or as a step towards quitting. A significant minority thought that light cigarettes were less harmful than regular cigarettes 83. A longitudinal study in the US found that smokers who switched to lower tar cigarettes found that they were no more likely to make a quit attempt or to achieve cessation over a two year period compared with those who did not switch to a lower yielding brand. Indirectly there was a suggestion that switching to lower tar brands influenced cessation by moderating motivation to quit 84.

The fact that smokers switched to low cigarettes rather than quitting reflected the stated intent of the tobacco industry 85. Internal industry documents clearly established that low tar cigarettes were being sold and marketed with the primary purpose of convincing the public that these products were safer and keeping smokers in the franchise.

The net effect of this may therefore have been an increased number of smokers. As a result, the EC banned the use of these and similar terms and graphics to suggest that some products were less harmful than others.

From 30 September 2003 therefore the terms light/mild/low tar were removed from packs in the EU, although there is some indication that the brand identities and colours of light cigarettes was established a considerable time ago so that little work would be needed to maintain the differentiation in the future. Tobacco industry documents indicate that a wide range of colours and designs were market tested with consumers to determine which were more effective at conveying an image of reduced strength and how the packaging can influence perceptions of the smoking experience 86. The main response to the ban on misleading descriptors has therefore been to distinguish brands by the use of colours. For example Imperial Tobacco changed its Lambert & Butler Lights pack to be renamed Lambert & Butler Gold, whereas the Ultra cigarettes were named White. Silk Cut Ultra have been renamed White by Gallaher. Some companies are also using the word smooth instead of the light/low tar descriptors. Philip Morris responded with an advertising and information campaign emphasising the dangers of lower tar cigarettes. The impact of these responses is not known and should be monitored.

In order to emphasise the dangers of low tar cigarettes, Cancer Research UK and the Department of Health ran an advertising campaign in September 2003 in the UK entitled '*Death Repackaged*' which highlighted the misapprehension that low tar cigarettes are in some way healthier than conventional regular cigarettes.

Recommendation:

- The impact of the ban on misleading descriptors on smoking behaviour and the response of the tobacco industry needs to be closely monitored.

The need for generic packaging

Tobacco advertising restrictions have resulted in cigarette packaging becoming more important as a component of tobacco marketing with sophisticated point of sale marketing strategies focusing particularly on brand imagery 86. Tobacco industry documents have shown that in addition the careful use of colours, pack designs are extensively researched with particular designs being developed to appeal to specific target audiences such as young adults and women.

In order to disrupt these marketing strategies, generic packaging should be introduced at least for the most hazardous combustible tobacco products and its impact monitored.

Recommendation:

- Generic packaging should be introduced at the very least for the most hazardous combustible tobacco products

Consumer information concerning products proven to reduce harm

Although terminology suggesting some tobacco products are less harmful than others is currently banned in the EU, if some tobacco products are identified as being 'significantly' less harmful than others, then consumers have a right to know and consideration needs to be given as to how this information can be best communicated. This is an important issue as in the absence of claims, new products are unlikely to be taken up, particularly if they are not as satisfying as cigarettes. Indeed in the US, a smokeless tobacco company, UST, has requested an advisory opinion from the US FDA on whether it can advertise that its smokeless tobacco products are less harmful than cigarettes.

However, the downsides of promoting a product as harm reducing, discussed in detail in relation to low tar cigarettes above, is that a net negative public health impact might result if they caused some cigarette smokers who might have quit to switch, attracted some new users and caused some ex-smokers to relapse to the less harmful product and therefore become tobacco users once again.

The IOM report [6](#) recommended that claims of risk reduction should only be made after the product had being approved by the regulators based on scientific evidence:
(a) that the product substantially reduced exposure to one or more tobacco toxicants, and
(b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with a specified benchmark product.

The IOM report also recommended that if a claim for risk reduction was not being made the product could be brought to market without prior agency approval providing it was not expected to increase risk compared to similar conventional tobacco products. Together, these recommendations could have the effect of entrenching the status quo, as the barriers become greater for products making claims of risk reduction which means that there is little incentive to bring products with reduced risk to the market. We therefore believe that all new tobacco products should have prior approval and that manufacturers should be able to demonstrate that the products have the real potential to significantly reduce harm compared with conventional tobacco products on the market. Over time, all existing tobacco products (hence not only new tobacco products) would need to adhere to similar regulatory requirements.

The key challenge will be in defining what is an acceptable 'significant' reduction in harm compared to cigarettes. Some experts have argued that if a product is an order of magnitude lower in risk then there is an obligation for the consumer to be given that information [63](#). Kozlowski also suggested that strong communication was needed of the messages arising from the risk equilibrium model, meaning strong communication of the fact that medicinal nicotine is significantly less harmful than cigarettes [56](#). However, it will be critically important that the content and delivery of this information is controlled and specified by the regulator, not the manufacturers.

The tobacco industry has a history of using very sophisticated marketing strategies and a variety of promotional techniques based on comprehensive market research. There is also evidence that the industry has successfully targeted young people, poorer smokers and other vulnerable groups. The industry has been quick to exploit any loopholes in legislation, and as a result the industry should not be trusted to communicate any risk reduction information in a manner which might expand the overall market. We therefore recommend that all promotional bans on tobacco products should be maintained as new tobacco products will still cause harm.

At the other end of the spectrum, as discussed above, the pharmaceutical industry is very tightly regulated with strict controls on claims they can make but the marketing and labelling restrictions around these products means that they cannot compete successfully with cigarettes.

All consumer information on tobacco and nicotine products should be under strict regulatory control **but** in order that the products need to be able to compete with cigarettes, where there is a 'significant' reduction in harm, this needs to be communicated by regulators, in an accessible way making the products attractive to smokers. For this reason, consumer information concerning NRT products needs to be considered within the same framework as communications around cigarettes and other tobacco products. These issues are complex as we have seen in the previous section as words, style and the use of colours can constitute harm reduction claims.

Recommendations:

- Regulators need to agree what constitutes a 'significant' reduction in harm
- Where there is 'significant' reduction in harm, regulators need to have strict control and specification of the harm reduction messages
- Most if not all changes to cigarettes will *not* have a significant impact on public health and the changes should be made mandatory with no information being given about them
- All promotional bans on tobacco products should be maintained as new tobacco products will still cause harm
- Comprehensive research and surveillance of any communication of harm reducing messages and of the impact of the messages and products would be needed

Traceable markings

The directive specified the need for traceable markings on tobacco products. We are not aware of any technical measures that have been laid down for this but we understand from HM Customs & Excise that companies are marking their products in this way although these codes are not decipherable outside of the tobacco industry. It is critically important that a common system is developed for these markings which can then be deciphered by regulators independently of the industry. This is essential to improve understanding of the smuggling and counterfeit cigarette markings.

Recommendation:

- The industry should provide the means by which regulators can decipher the traceable markings on tobacco products without recourse to manufacturers. A common system for these markings should be developed across the industry

7 Regulatory committee meetings

The regulatory committee set up under Article 10 of the directive to support its implementation held its first meeting in September 2002. The published minutes [87](#) indicate that the members of the committee were largely representatives from the Ministries of Health in Member States. The first meeting mainly discussed the preliminary draft of the Commission Decision on the use of colour photographs or other illustrations to depict and explain the health consequences of smoking. The second meeting held in February 2003, and the published minutes [88](#) indicate that there was further discussion on the draft Commission Decision on the use of colour photographs (the final version of which was published in September 2003). The committee also discussed national implementing legislation for the Directive and the need for a standard format for the presentation and assessment of ingredients data. Although a further meeting was suggested for November 2003, it is not known whether this meeting went ahead.

8 The need for an independent tobacco regulatory agency both within the UK and Europe

A consistent theme throughout this report has been the need for adequate regulatory capacity within the UK and the European Union. In the UK, a number of bodies have now called for a Nicotine and Tobacco Regulatory Authority (NTRA) to be set up, acknowledging that there is no adequate institutional framework to analyse, assess and regulate nicotine and tobacco products [589](#). The House of Commons Health Select Committee [90](#) described the resources devoted by the UK Government to tobacco regulation as 'pitifully weak' and at a European level as 'utterly derisory' and to our understanding, there has been no significant increase in staffing and resources since that report at either level. The need for greater regulatory capacity is now urgent given the fact that alternative tobacco and nicotine products are evolving rapidly and several novel tobacco products are already under evaluation in other countries.

Government response to date has been to suggest that such an authority should be set up a European level [91](#). We believe that there should be a dedicated European body for tobacco and nicotine, but it is clear that given the 114,000 deaths each year in the UK from tobacco require that significant regulatory expertise is required at national level as well. In addition, it may take some time for a European body to be set up but action is needed urgently to address the many and complex issues raised in this report.

Precedents exist for regulatory bodies both at a UK and European level in a number of other health fields. For example in the field of nutrition, there is a Food Standards Agency (FSA) in England as well as a European Food Safety Agency (EFSA). For medicines regulation, Member States have medicines regulatory bodies and in addition there is a European Medicines Evaluation Authority. Both the national bodies for food and medicines have large resources and capacity and the contrast between smoking and these other areas of public health is instructive. The Food Standards Agency has a staff of over 2000 (including the Meat Hygiene Industry but excluding scientific and advisory committee staff) and a budget of over £107 million in 2001/02. The MHRA (the Medicines and Healthcare products Regulatory Agency, the medicines regulatory body for the UK) obtained a budget for 2000/1 of £38.4 million and has 436 employees. The MHRA was previously managed within the Department of Health but is now separately staffed and accountable with autonomous funding, a model that we suggest would also be appropriate for the regulation of tobacco.

This section builds on previous work in this area (ref RCP) and discussed the key issues involved in setting up such bodies. In addition, templates have been developed for the aims and objectives of independent nicotine and tobacco regulatory authorities at the UK and European level (Figures 8 and 9).

Funding

There are several options for funding such a body for example through taxation or a licensing system. A licensing system across all aspects of the tobacco chain from manufacturers through to exporters would be similar to the funding of the food and medicines regulators although some government funding is also involved in the food regulatory bodies.

Maintaining independence of the industry

If funding was derived through licensing the tobacco industry it would be critically important to prevent regulatory capture by the industry and therefore the regulators and regulatory process

would have to be completely independent from the industry. This would be a fundamental difference from the other regulatory bodies discussed above which have representatives on the Board from the relevant food and pharmaceutical industries. It would also be a significant departure from previous practice in tobacco control as in recent decades the tobacco industry entered into a series of 'gentlemanly' voluntary agreements with the government, although there is wide consensus that these voluntary agreements were ineffective 92.

Tobacco is an anomaly as there is no other consumer product on the market which kills one out of two of its users. Indeed if it wasn't for an accident of history, cigarettes would not be allowed on the market today. Furthermore, the tobacco industry has a history of manipulating the truth and regulators as revealed by the litigation process in the US which forced the industry to release their documentation. One ASH document 93 indicates *'that denial, deceit, and obfuscation are the major tools of the tobacco trade'*. Although some companies have engaged in public relations exercises over the last few years to indicate that they are reformed organizations, the history of manipulation is too compelling to allow industry engagement in the regulatory process.

Tobacco therefore requires a different regulatory approach and the tobacco industry should not play any role in the management and decision making of the authority.

Implementing a Nicotine and Tobacco Regulatory Authority in the UK

The RCP examined the legislative basis for the proposed NTRA. The most favoured approach involved primary legislation but the report noted that existing legislation such as the Consumer Products Act and the Medicines Act could be utilised to implement new regulatory controls on tobacco.

Appropriate institution with sufficient authority independent of government

For the UK body there appear to be three different types of agency which could be set up:

- Non Ministerial Government Departments such as the Food Standards Agency, HM Customs & Excise, or the Inland Revenue
- Non governmental public bodies such as the Environment Agency
- Executive Agencies eg the Medicines and Healthcare products Regulatory Authority

Non-Ministerial Government Departments have specific statutory responsibilities and are staffed by civil servants. The nature of the relationship with Ministers appears to vary 94 95. For example some organisations such as the Inland Revenue and Customs & Excise work closely with Ministers whereas other bodies, such as the Charity Commission implement legislation which they cannot change. The general rationale appears to be to distance administration of the activity from direct Ministerial control whilst retaining Government input to the wider policy context. Non-Ministerial Government Departments are:

'.. politically independent by being government departments, budgets are set by Treasury and they are often funded by licence fees paid by the industries which they regulate.' 96

Non-governmental public bodies and executive agencies vary widely in their remits, some having an advisory role, others having an executive function. They are not directly accountable to Ministers being accountable to Parliament, but are funded by a particular Department which can affect the independence of the body. Executive agencies undertake the executive function of government as distinct from policy advice 94.

An essential precondition for setting up Executive Agencies is:

'Areas of work where the day-to-day involvement of the Department of Ministers is inevitable, or where policy and its execution are inextricably linked, are unlikely to be suitable candidates for

agency status.presumption must be that, provided that management is operating within the strategic framework set by Ministers, it[the agency] must be left as free as possible to manage within that framework'.

Although the distinction between the different bodies is not always entirely clear cut, given the interrelationship between policy and implementation in this area, we suggest an Executive Agency is not likely to be an appropriate model for the NTRA. A Non Ministerial Government Department (NMGD) would appear to provide an appropriate level of authority which is politically independent. If an NMGD was the most appropriate body a licensing system is the most usual funding system. The Food Standards Agency would appear to be a very useful model of NMGD:

'The Food Standards Agency is a very special case in that it is an NMGD which was created by merging two large parts of the Departments of Health and what was then the Ministry of Agriculture, Fisheries and Food. The aim was to reassure the public (after the BSE/vCJD crisis) that decisions about food safety would in future be taken by an eminent and independent body free of political control. However, Ministers asked the FSA to continue to negotiate on their behalf in Brussels, rather than re-create shadow policy directorates within the original two departments. But because the FSA was designed to take politics out of food safety, it does not seek Ministerial approval for its negotiating position. Indeed, it agrees to European legislation on behalf of the UK, whereupon Ministers find themselves promoting and defending policies (i.e. when implementing the resultant European legislation) which they neither influenced or approved. This is constitutionally deeply unsatisfactory but perhaps pragmatically necessary, and maybe a nice example of the flexibility of the UK's unwritten constitution' [96](#).

Much can be learned from the remit of the FSA which specifies that it provides advice and information to both the Government and the public on food safety across the food chain, it protects consumers through effective monitoring and enforcement and supports consumer choice by promoting accurate and meaningful labelling. It works with a variety of different individuals and organisations including Government departments and agencies, consumers, consumer organisations, manufacturers, retailers, farmers, local authority enforcement teams and the catering agency. The Food Standards Agency states that much of their work '*depends on understanding and dealing with risk*'. An explanation of how they approach risk is available [97](#). The Food Standards Agency emphasizes the importance of keeping up with the science in doing its work and has in-house experts as well as a number of scientific advisory committees and in addition, commissions its own research and surveys.

Timescale for implementation

Agencies of this nature can be set up relatively quickly. For example, the Food Standards Agency was set up over a period of three years, beginning with the first recommendations on the structure and functions of the Agency being commissioned in March 1997, the passing of the Food Standards Act in November 1999 which established the FSA, and the Agency becoming operational in April 2000 in accordance with the Act.

An example at the European level is the new European Centre for Disease Prevention and Control (ECDC) which was agreed by Health Ministers in May 2003 following evaluations of existing networks and systems, first conducted in 2000. The Commission is aiming to have the ECDC start work in 2005.

Scope

Earlier in the report, the need to regulate all nicotine delivery systems within a single regulatory framework was discussed. This is critically important if the market is to be shifted in favour of the less harmful systems. The feasibility of taking therapeutic nicotine products outwith the medicines regulators needs to be assessed and such a move may be resisted by the pharmaceutical

manufacturers. Options to achieve a single regulatory framework need to be further explored. One possible solution might be to maintain the different regulators but to share information across the regulatory bodies, perhaps through a 'concordat', with strict and specified public health goals.

Tobacco product modification and harm reduction must take place within a comprehensive and integrated tobacco control strategy. Ultimately we therefore believe that the authority should manage all aspects of tobacco control but it is possible that initially the authority focuses on tobacco product regulation only. Figure 8 specifies a template for a UK regulatory body which would manage all aspects of tobacco control.

A European regulatory tobacco authority

At the European level, the implementation of the Amsterdam Treaty has increased the public health responsibilities of the European Union. Article 3 of the Treaty calls for the activities of the Community to contribute to the attainment of a high level of health protection. Article 129 of the Treaty also provides for Community action to be directed towards the prevention of diseases, in particular the major health scourges. Article 152 of the Treaty stipulates that community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health.

The Community has already adopted a range of measures to help counter tobacco consumption, most of which have been introduced in order to harmonise the Single Market, with some others being adopted under the Treaty provisions governing public health. The current EU directive built on two previous directives in introducing further controls on product regulation and labelling. Greater regulatory capacity is still needed at a European level to put tobacco on a par with food and medicines regulation and in order to have the ability to steer the nicotine market in favour of public health. A European regulatory authority is therefore urgently needed.

There are precedents for setting up European regulatory bodies even when similar bodies do not exist at Member State level. The new European Centre for Disease Prevention and Control (ECDC) which was agreed by Health Ministers in May 2003 was set up in the absence of similar bodies within Member States. In instigating this agency the Commission commented that:

'the structure of the existing EU network on communicable diseases was not efficient enough to protect the EU's citizens sufficiently against threats to the health posed by communicable diseases, including the possibility of the deliberate release of infectious agents ("bio-terrorism")'

Similar arguments can easily be made about the growing tobacco epidemic across the EU.

In its Programme for 2003 to 2008 98, the European Commission has identified the following areas as important for tobacco control:

- Smoking Prevention & Cessation – encouraging and supporting action networks, for information gathering and provision with regards to promoting strategies focusing on cessation and health education, protecting the population from the risk of passive smoking, denormalising smoking and assessing legislative measures on tobacco control.
- Tobacco control – a comprehensive legislative programme to tackle smoking. Future action to be taken in scientific and technical support regarding :
 - the follow up of the Decision on colour photographs/illustrations as additional health warnings
 - legal data collection, scientific and technical advice on ingredients
 - background information and analysis of country situations in order to provide tobacco reports on the implementation of the Tobacco Products Directive and on the Community's tobacco control policy

It is unlikely that these actions will do enough to stem the tobacco epidemic. A new review commissioned by the European Commission is examining future priorities in tobacco control for the Commission.

The proposed European Tobacco Regulatory Authority would greatly expand tobacco control efforts across Europe. A template for a European organisation is shown in Figure 9. In this template the remit focuses solely on tobacco product regulation issues (unlike the UK template) but with a view to regulating all aspects of tobacco control over a period of five to ten years.

More radical regulatory models

Borland [99](#) and Liberman [100](#) have advocated more radical solutions given the unique set of problems caused by tobacco and the 'perverse incentive' that exists for the tobacco industry to maximise profits by maximising sales (and consequent harm).

Liberman called for a new agency which would be responsible for structuring a regulatory system which incentivised the reduction of harm and which would have responsibility for ensuring that products were made available to those needing them but with no economic incentives for sales. Borland suggested the development of a Tobacco Products Agency (TPA) to regulate tobacco which would be in the form of a monopsony controlling the marketing of tobacco products. He referred to this as a Regulated Market Model. He indicated that the TPA would become the sole customer of manufacturers and importers and would control wholesale distribution to retailers. Borland argued that such an agency would be able to remove the incentives to promote tobacco by removing the direct link between manufacturers and consumers. In addition, the TPA would have the capacity to withdraw more harmful products from the market and would provide incentives to manufacturers to product less harmful products. His paper discusses the model in detail and addresses concerns such as reducing the risks of regulatory capture by either governments or the industry.

The feasibility of setting up such agencies in free trade societies needs to be examined further.

Recommendation

- Nicotine and Tobacco Regulatory Authorities need to be set up urgently at both UK and European levels

Figure 8 Tobacco and Nicotine Regulatory Authority

- An independent tobacco watchdog
- Set up by an Act of Parliament
- To protect the public's health and consumer interests in relation to tobacco
- A non-Ministerial Government Department (eg FSA)
- UK wide body, HQ in London
- Links with devolved administrations in Scotland, Wales & N Ireland and other government departments
- Links with EU and other international organisations
- Accountable through CE to a Board who are in turn accountable to Government
- Free to publish any advice it issues

Guiding principles:

- Putting consumers first
- Being open and accessible
- Being independent
- To shift the nicotine market towards the minimization of harm

Key Aims - to reduce tobacco mortality and morbidity by:

- Regulating the tobacco industry through a comprehensive licensing system, from production to manufacturers to wholesalers (importer & exporters) to retailers – including issues around product tracking, access, promotion, labeling, sales etc
- Regulating the tobacco product by controlling product manipulation – this includes controls over disclosure, standard setting, additives, other tobacco constituents, inspection and enforcement, consumer protection through informative and accurate labeling, all across the range of tobacco and related nicotine products
- Public education programmes to reduce smoking prevalence
- Research and evaluation – a comprehensive programme of research around smoking behaviour and other aspects of tobacco control, monitoring, surveillance and evaluation of the Authority's activities

Structure:

- Board – appointed to act collectively in the public's interest. Variety of skills and experience excluding those with any financial or other interest with the tobacco industry.
- Budget – derived mainly through a licensing system of tobacco across the tobacco chain

Figure 9 European Tobacco Regulatory Agency (ETRA)

- Established by a Regulation of the European Parliament & Council which would provide basis for high level of protection of human health & consumers' interest in relation to tobacco, taking into account diversity in tobacco supply & traditional products, whilst ensuring effective functioning of internal market
- Community body with own legal identity
- Operates independently of Community institutions
- A scientific risk assessment body; responsibility for risk management or decision making remains with EU's political institutions
- Develop and issue scientific and technical information on a wide range of matters affecting safety of tobacco chain
- Extensive responsibilities for communicating scientific and technical information directly to public in a coherent & consistent manner
- Covers all stages of tobacco chain
- Objective – to ensure that its independence, scientific excellence and openness will make the Authority the first port of call on matters relating to tobacco

Responsible for:

- The scientific evaluation of risks pertaining to all nicotine and tobacco products
- The collection & analysis of scientific data
- Identification of emerging risks
- Scientific support to the Commission
- Direct communication to the public & other interested parties of information concerning matters within its remit

Structure:

- Managed by an Executive Director who is answerable to a Management Board
- Board to be appointed to secure highest standards of competence, broad range of relevant expertise and broadest possible geographic distribution within the EU. Excluding those with any financial or other interest with the tobacco industry
- An Advisory Forum to advise and enable exchange of information and networking with competent bodies in Member States
- Scientific Committee and Scientific Panels will be set up responsible for providing scientific opinions of the Authority, within own sphere of competence
- Located temporarily in Brussels
- Budget – mainly through a licensing system of tobacco across the tobacco chain

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Appendix 1 – ISO standards

ISO 4387 means the International Standard entitled:

Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical cigarette-smoking machine ISO 4387: 2000 third edition published by the International Organisation for standardisation on 6 April 2000

ISO 8243 means the International Standard entitled:

Cigarettes – Sampling ISO8243: 1991 second edition published by the International Organisation for Standardisation on 15 October 1991

ISO 8454 means the International Standard entitled:

Cigarettes – Determination of carbon monoxide in the vapour phase of cigarette smoke – NDIR method ISO 8454: 1995 second edition published by the International Organisation for Standardisation on 15 November 1995

ISO 10315 means the International Standard entitled:

Cigarettes – Determination of nicotine in smoke condensates – Gas-chromatographic method ISO10315: 2000 second edition published by the International Organisation for standardisation on 30 March 2000

Appendix 2 – WHO Framework Convention on Tobacco Control

Several clauses made reference to tobacco product regulation and packaging as follows:

Article 9

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

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 governmental 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.

Article 11

Packaging and labelling items

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:
 - a. tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and
 - b. each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:
 - i. shall be approved by the competent national authority,
 - ii. shall be rotating,
 - iii. shall be large, clear, visible and legible,
 - iv. should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
 - v. may be in the form of or include pictures or pictograms.
2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.
3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and

- package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.
4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

Appendix 3 – Recommendations in full

Methodologies for more realistically assessing and regulating toxic exposure and harm

- There should be no further reductions in machine based maximum tar/nicotine yields
- It is too early to comment on the potential impact of the new limit on CO yields
- ISO tests should no longer be used as the basis for cigarette regulation
- 'Tar' should no longer be used in the regulation of tobacco products but be replaced with different constituents of tobacco and/or tobacco smoke
- Future measurement tools should take into account the role of nicotine in tobacco use
- Cleaner nicotine delivery systems should be made more accessible than cigarettes and other forms of combustible tobacco
- It is important to have nicotine under regulatory control and the limit of 1 mg/cigarette nicotine yield is an important first step in this process.
- Further research is needed as to whether the proportion of freebase nicotine affects the addictive properties of tobacco products and its relationship to ingredients and additives.
- An array of assessments across a number of dimensions are needed to regulate tobacco products. The complexity of these regulations requires much greater regulatory capacity for tobacco product regulation than is available currently.
- A proper regulatory framework needs to be established monitoring a number of different aspects of the cigarette including physical and chemical characteristics, emissions (to smokers and non-smokers), human exposure, biomarkers etc. Regulators are obliged to monitor physical and chemical characteristics of tobacco products over time.
- All new products should be fully characterised and before entry to the market the manufacturers should demonstrate that they have real potential to significantly reduce the harmfulness of the product.
- Suggestions that have been made to adapt the FTC/ISO tests to more closely approximate smoking behaviour still will suffer from the fact that no single puffing regime will reflect how smokers behave. Nevertheless, capped ratios of individual carcinogens to nicotine using modified and standard ISO test regimes may still be useful metrics to monitor as part of the regulatory framework.
- Setting current median levels of constituents as maximum levels per mg of tobacco and possibly as a proportion of whole smoke should also be given serious consideration.

- A tobacco products regulatory framework needs to take account of the growing use of hand rolling tobacco in the UK
- Hand rolling tobacco does not lend itself easily to regulation
- Regulators should require full characterisation and disclosure of hand rolling tobacco products from manufacturers
- Setting standards and toxins per mg of tobacco or per mg of tar would appear to be the only meaningful regulatory measure that could be used for hand rolling tobacco products.

Ingredients

- The tobacco industry is currently not complying with the requirements of the directive concerning ingredient disclosure
- The current directive can be improved in several ways, for example in how ingredients are defined
- The toxicity of most additives is considerably less than the toxins in tobacco smoke and hence regulations around additives are unlikely to make a significant impact on public health
- There is a compelling case for banning all additives unless they meet a test of public health or public interest with the burden of proof being on the industry.

Potential less harmful products

- All tobacco and nicotine products should be evaluated within a single regulatory framework in order to shift the nicotine market in favour of cleaner forms of nicotine delivery over the next few decades
- Regulators controlling therapeutic nicotine products need to take account of what happens if these products are not used
- The most promising harm reducing products are non-combustible nicotine delivery systems. Currently this includes NRT and some forms of smokeless tobacco
- Immediate steps should be taken to correct the widespread misunderstandings about the role of nicotine and the risks of NRT and broaden their access in terms of lifting restrictions on their use for some population groups, lifting restrictions on uses other than cessation, and enabling the purchase of NRT through a wider variety of retail outlets.
- Steps should be taken to incentivise the production of clean recreational nicotine delivery systems
- If the ban on smokeless tobacco is removed, this should only be done within an evidence based regulatory framework which sets standards for carcinogens and other toxins for all forms of tobacco

Consumer information

- Tar, nicotine and CO yields need to be removed from packs

- The desired impact of consumer information should be clarified. We believe it should be aimed at encouraging and facilitating smokers to successfully reduce their risks and quit smoking
- Consumer research is needed on what information should be communicated instead and how best to do this
- Pictorial health warnings should be adopted when this becomes possible later this year. These should be accompanied by messages which are supportive and facilitate quitting
- All health warnings and messages will need to be pre-tested and should be continually refreshed and revised if they are to remain impactful
- The impact of the ban on misleading descriptors on smoking behaviour and the response of the tobacco industry needs to be closely monitored
- Generic packaging should be introduced for all tobacco products
- Regulators need to agree what constitutes a 'significant' reduction in harm
- Where there is 'significant' reduction in harm, regulators need to have strict control and specification of the harm reduction messages
- Most if not all changes to cigarettes will *not* have a significant impact on public health and the changes should be made mandatory with no information being given about them
- All promotional bans on tobacco products should be maintained as new tobacco products will still cause harm
- Comprehensive research and surveillance of any communication of harm reducing messages and of the impact of the messages and products would be needed
- The industry should provide the means by which regulators can decipher the traceable markings on tobacco products without recourse to manufacturers. A common system for these markings should be developed across the industry

The need for a regulatory authority

- Nicotine and Tobacco Regulatory Authorities need to be set up urgently at both UK and European levels

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