REGULATION OF TOBACCO PRODUCTS: AN UPDATE ON EUROPEAN DEVELOPMENTS 1999-2001

WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR EUROPE

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by Luk Joossens

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This paper is a product of the WHO European Partnership Project to Reduce Tobacco Dependence. The WHO European Partnership Project to Reduce Tobacco Dependence was set up in 1999, for an initial three-year period, with the objective of reducing tobacco-related death and disease. The Partnership Project comprises private, non-commercial and public sector partners, including the pharmaceutical sector at the European level and in four target countries, France, Germany, Poland and the United Kingdom. In 2001, the Czech Republic joined the project.

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Introduction

Tobacco-caused morbidity and mortality presently accounts for approximately 1.2 million deaths each year in the European Region. On current trends, this rate will increase to approximately 2 million deaths by 2020. Efforts to control tobacco related death and disease are a cornerstone of the work of the WHO and many other governmental and nongovernmental agencies.

The cigarette is the only consumer product that kills when used as intended by its manufacturers. It is a highly engineered delivery system for the drug nicotine, yet compared to food and pharmaceuticals it’s content, yield and delivery is virtually unregulated. A comprehensive tobacco control strategy should therefore include a framework within which tobacco can be appropriately regulated.

In 1999, the World Health Organization Regional Office for Europe held a conference on the regulation of tobacco products in Helsinki. The purpose of the conference was to identify the most appropriate regulatory actions that need to be considered as part of comprehensive efforts to reduce smoking attributable death and disease and to suggest regulatory changes that could lead to improved public health. The conclusions of this conference are available (WHO Europe, 1999). This report discusses recent developments in tobacco product regulation.
Recent developments in Tobacco product regulation

Since the Helsinki Conference on the regulation of tobacco products several important developments have occurred. The WHO has established an international advisory committee on tobacco product regulation, negotiations are underway on the Framework Convention on Tobacco Control including proposals for tobacco product regulation, and the European Parliament and the Council have adopted Directive 2001/37/EC on the regulation of tobacco products. These three developments will be described and discussed here in more detail.

An international advisory committee on regulation of tobacco products

The WHO’s Tobacco Free Initiative (TFI), in collaboration with the Norwegian Ministry of Health, organized an International Conference on regulating tobacco products in Oslo, in 2000. The conference was attended by representatives from 20 countries from all WHO regions and the objectives of the Conference were to:

• Exchange scientific information about tobacco product design and manufacture needed for regulation.
• Define public health goals of regulation of tobacco products and how concepts such as “safer cigarette and harm reduction” fit within such goals.
• Identify priority research areas required in order to advance regulation of tobacco products.
• Consider administrative options for countries to use in regulating tobacco products.
• Recommend whether a protocol on regulation should be developed as part of the Framework Convention on Tobacco Control.

The proceedings of the conference were published in a WHO monograph and the conference recommendations are reproduced in Annex 1.

One of the outcomes of the Oslo meeting was the establishment of the WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob), which has been set up to facilitate access to scientific information and guide international policy development in the area of tobacco product regulation.

The committee will advise WHO on recommendations to governments on the most effective ways to achieve a coordinated regulatory framework for to-
bacco products. SACTob has 20 Members from 15 countries and has held meet-
ings in October 2000, January and July 2001. A report of the papers discussed
in the Oslo meeting has been published (WHO, 2001).

The Framework Convention on Tobacco Control

On 24 May 1999, the World Health Assembly (WHA), the governing body of
the World Health Organization (WHO), paved the way for multilateral nego-
tiations to begin on a set of rules and regulations that will govern the global
rise and spread of tobacco and tobacco products in the next century. The WHA
which has 191 members unanimously backed a resolution calling for work to
begin on the Framework Convention on Tobacco Control (FCTC) - a new legal
instrument that could address issues as diverse as tobacco advertising and pro-
motion, agricultural diversification, smuggling, product regulation, taxes and
subsidies.

The Working Group on the WHO Framework Convention on Tobacco Con-
trol held two meetings which were attended by participants from a wide range
of sectors and included representatives from 153 Member States (representing
95% of the world’s population) and the European Community.

In May 2000, the World Health Assembly unanimously adopted a resolution
which formally launched the political negotiations on the Framework Convention
which began October 2000.

A President’s Draft of the Convention was made available in January 2001.
Amongst other issues, this draft text contained several proposals on tobacco
regulation such as

- adoption of standards for the regulation of the contents of tobacco products,
  including standards for testing and measuring, designing, manufacturing
  and processing such products, and cooperation in the development and
  harmonization of such standards under the auspices of the World Health
  Organization;
- a ban on the use of the terms “low tar”, “light”, “ultra light”, “mild” or any
  other similar term that has the aim or the direct or indirect effect of convey-
  ing the impression that a particular tobacco product is less harmful than
  others on any unit packet or package of tobacco products;
- the preparation of a protocol setting out appropriate rules and procedures in
  the areas of regulation of the contents of tobacco products, tobacco-product
  disclosures, and packaging and labelling of tobacco products.

The President’s draft was discussed during the second session of negotiations
which took place in April/May 2001 and the third meeting of the Intergovern-
mental Negotiating Body for the FCTC is scheduled for late November 2001.
The aim of the negotiations is to have a convention ready for adoption by the WHO Health Assembly in May 2003.

**EU developments on regulation of tobacco products**


The Directive has to be introduced in the national legislation of the 15 EU Member States by 30 September 2002.

The main provisions in the Directive are the following:

- **Maximum yields:** From 1 January 2004, the yield of cigarettes, marketed or manufactured in the European union shall not be greater than:
  - 10 mg per cigarette for tar;
  - 1 mg per cigarette for nicotine;
  - 10 mg per cigarette for carbon monoxide.

  The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered (12% for two official languages and to 15% for three official languages).

- **Warning labels:** to cover 30% of the front of the pack (32% for two languages and 35% for three languages) and 40% of the back of the pack (45% for two languages and 50% for three languages)

- **Warning texts:** general warning on the front – either ‘Smoking kills (or ‘can kill’, depending upon transposition) or ‘Smoking seriously harms you and those around you’ to be alternated on a regular basis; additional warnings on the back.

- **Use of colour photos and graphics etc:** The Commission has been asked to prepare rules for the use of colour photos (e.g., as recently introduced in Canada), graphics etc by December 2002.

- **Reporting requirements:** Member States shall require the tobacco industry to submit to them a list of all ingredients used in the manufacture of those tobacco products. On the basis of the information required from the
industry, the Commission should submit a proposal by 31 December 2004 providing for a common list of ingredients authorised for tobacco products.

- Misleading descriptors: With effect from 30 September 2003, texts, names, trademarks 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.

- Traceability: batch numbers, or their equivalent, will have to be applied to each individual carton to ensure that the date and place of manufacture can be determined.

- Monitoring and review: Mechanisms will be introduced to ensure that the implementation of the Directive is properly monitored and that the provisions of the Directive are kept up-to-date in terms of scientific developments. The Commission shall submit in 2005 a report on the application of this Directive. With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available.
Some recommendations for moving ahead

In 1999 the Health Education Authority published its report “Consumers and the changing cigarette” (Evans & Joossens, 1999) and made four policy recommendations:

- require full disclosure by brand and by regulation of additives
- review the ISO standards that measure the tar and nicotine yields,
- remove unproven health claims on the packaging of tobacco products,
- provide more information to consumers.

These policy recommendations are still valid in view of the developments outlined above.

**Disclose all tobacco ingredients**

Although tobacco products are both widely used and complex devices, they have escaped meaningful regulation in part because of the lacunae in knowledge about them outside of the industry (Slade & Henningfield 1998).

More information is needed about the role of constituents, chemicals, flavourings and other additives. Before additives can be recognised as safe, the industry should be able to prove their safety when used as intended (for example, when burned in conjunction with other ingredients and additives). Gathering this information can be facilitated through an obligation to disclose all ingredients and additives in all tobacco products and by the tobacco industry reporting all major toxic constituents based on internationally accepted test methods.

Canada, Thailand and the U.S. States of Massachusetts and Texas all require testing of smoke constituents above and beyond the tar, nicotine and carbon monoxide tests. The new EC Directive obligates the 15 EU countries to require the tobacco industry 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. 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 for a common list of ingredients authorised for tobacco products.

The new EU legislation therefore provides new opportunities to acquire better knowledge of the content of tobacco products and is for many countries a first step towards better regulation of tobacco products, for instance by agreeing on a common list of authorized ingredients.
The Directive is also a challenge as more expertise is urgently needed within Europe to understand and analyse the massive amount of information which will be provided to the regulators. Health organisations must become involved in this complex area of tobacco regulation. In a recent article, Bialous and Yach of the WHO Tobacco Free Initiative have argued that the tobacco industry has dominated the process of tobacco and the setting of tobacco products measurement standards to advance its political and commercial needs, therefore preempting the passage of regulatory policies that would indeed protect the health of the public. (Bialous & Yach 2001) More independent laboratories, more expertise and more independent scientists are needed in order to achieve meaningful regulation of tobacco in Europe.

**Review ISO standards**

The European Union has set maximum yields per cigarette. From 1 January 2004, the yield of cigarettes, marketed or manufactured in the European Union shall not be greater than:

- 10 mg per cigarette for tar;
- 1 mg per cigarette for nicotine;
- 10 mg per cigarette for carbon monoxide.

The European legislation stipulates that reference should be made to ISO standards when measuring the tar, nicotine and carbon monoxide yields of cigarettes. The standard smoking machine using ISO standard procedures uses 35 ml puffs over 2 seconds repeated every 60 seconds until the cigarette burns down to a predetermined butt length. The tar and nicotine residues drawn into the machine are then measured.

However, it has been demonstrated that test results do not provide consumers with meaningful measures of what they can expect to ingest from cigarettes (ref RCP report?). In general, the ISO standard methods underestimate the tar and nicotine levels of cigarettes as people simply do not smoke like machines. Criticisms of the ISO standards have intensified over recent years. (Bates et al, 1999; RCP, 2000; Gray, 2000; Wilkenfield et al, 2000 and Bialous & Yach 2001, Jarvis et al, 2001).

One of the findings of an International Expert Panel on Cigarette Descriptors convened by the Canadian Ministerial Advisory Council on Tobacco Control in August 2001 (International Expert Panel, 2001) was that the machine smoking yields are irrelevant to assessing human disease risk. Nicotine-seeking results in smokers obtaining a set addiction-satisfying dose of nicotine from any design of cigarette. As a result, machine yield numbers have no significant health meaning for individual smokers. Hence, machine-smoking yields pro-
vided by companies are as misleading to regulators as they are to consumers. This deception is augmented by the use of deceptive branding descriptors which offer false health reassurance and may be perceived as describing a product that is less harmful, and therefore an alternative to quitting.

Although ISO standards are heavily criticized, there is still no international agreement on an alternative for the ISO methods. The use of ISO standards in the Directive is justified as they

“are the only internationally recognised standards, it being understood that subsequent research and technological progress to be promoted should make it possible to develop and use more precise and reliable measurement methods for cigarette yields and to develop measurement methods for the other tobacco products.” (recital 14 of the Directive 2001/37/EC)

The need for new valid international agreed measurement methods becomes more urgent and could be one of the important outcomes of the negotiations of the WHO Framework Convention on Tobacco Control.

**Ban misleading descriptors**

Based on surveys in Canada and the US, Joanna Cohen (2001) of the University of Toronto has summarized the public perceptions of the meaning of “Light” and “Mild” labelling in the following way:

- **Risk of disease:** substantial number of Light and Mild (L/M) smokers think L/M cigarettes reduce the risks of disease, and the smokers of “ultra” L/M are most deceived.
- **Tar delivery:** only a minority of smokers knows that “light” cigarettes can deliver the same amount of tar as regular cigarettes
- **Filter vents:** only a minority of L/M smokers know that blocking filter vent holes increases tar delivery
- **Reasons for smoking L/M:** about one half of L/M smokers say they smoke L/M cigarettes to reduce the risks of smoking
- **Likelihood of quitting if L/M deception is exposed:** substantial numbers of L/M smokers say that they would be likely to stop smoking if they found out that L/M cigarettes could deliver the same amount of tar and nicotine as regular cigarettes.
Research undertaken in Geneva (Switzerland), England and The Netherlands came to similar conclusions:

- England: A third of the smokers who currently smoked light cigarettes said that a main reason for switching to a light brand was because they were worried about their health. Almost three out of ten smokers also said that a main reason for switching was a step towards quitting. Over a quarter of smokers thought that light cigarettes were less harmful than regular cigarettes. More than a third of the smokers currently smoking light cigarettes thought them to be less harmful than regular brands. (research among 1036 adult smokers in England, October 1998. Source: Evans & Joossens, 1999)

- Geneva: Over a quarter of smokers and ex-smokers answered that the risk of lung cancer was lower in smokers of light cigarettes compared to smokers of regular cigarettes, 60% that the risk was the same, 7% that the risk was higher, and 7% gave no answer. For ultra light cigarettes, the corresponding figures were 32%, 55%, 6% and 7%. (Mail survey in a population sample of 494 smokers and ex-smokers in Geneva, Switzerland, in 1999. Source: Etter et al, Article submitted for publication, 2001)

- Netherlands: only one third of the smokers knew that blocking filter vent holes make a huge (10.7%) or a small (23.2%) difference for the intake of nicotine. A quarter of the smokers believed that light cigarettes were much less (5.5%) or some less (21.8%) harmful than regular cigarettes. (Source: “Continu onderzoek rookgewoonten 2000. Personen van 15 jaar en ouder.” (Amsterdam: NIPO), at the request of DEFACTO, N=1031. Unpublished data)

An International Expert Panel met on 27 and 28 August 2001 in Canada and made the following recommendation:

“There is an existing and false perception regarding cigarettes that are labelled with terms such as 'light' and 'mild'. Evidence establishes that Canadian smokers mistakenly believe that there is a reduction in disease risk that results from smoking cigarettes labelled with the terms 'light' and 'mild'. Evidence also establishes Canadian smokers mistakenly believe the use of cigarettes labelled light and mild will reduce their intake of tar and nicotine.”
And

“We conclude that a complete prohibition of the use of deceptive descriptors such as ‘light’ and ‘mild’ on cigarette packaging and marketing is necessary to ensure that past deception is redressed and ongoing deception is prevented. In addition, in order to prevent future deception, the regulations should also restrict the use of other words, colours or devices that result in an erroneous perception of a difference in health risks and/or tar/nicotine deliveries. To be effective, these regulations should be accompanied by a substantial education component to correct this dangerous and persistent misperception and by a mechanism to implement further measures if warranted.”

During the last year governments around the world have taken initiatives to ban deceptive labelling on tobacco products.

• Brazil: misleading terms such as mild and light on the packaging and advertising of tobacco products will be forbidden from 31 January 2002. (Resolution 46 of 26 March 2001)
• European Union: texts, names, trademarks 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 marketed or manufactured in the European union from 30 September 2003. (Directive 2001/37/EC of 5 June 2001)
• Canada: the Health Minister requested on 31 May 2001 that Canadian tobacco product manufacturers voluntarily remove descriptors such as ‘light’ and ‘mild’ from cigarette packaging, based on long-standing concerns that such descriptors are confusing to consumers. He also requested that his newly formed Advisory Council suggest a course of action in the event that the industry does not opt for a voluntary withdrawal.

The Chair of the Intergovernmental Negotiating Body (INB) of WHO Framework Convention on Tobacco Control proposed in its draft text of January 2001 to ban misleading descriptors and received support from many countries during the second meeting of INB in May 2001.

The tobacco industry (British American Tobacco, Imperial Tobacco and Japan Tobacco) and the Federal Republic of Germany and Luxembourg have already announced that it will challenge the EU Directive in court. Whilst BAT and Imperial Tobacco challenge several provisions in the Directive (such as the size of the warnings, the export provisions and the legal basis), all three companies will
also challenge article 7 of the Directive, which bans misleading descriptors on the package of tobacco products. The Federal Republic of Germany and Luxembourg have announced to challenge the export provisions of the Directive. It is hard to see how describing a product that kills one of two of its consumers as ‘light’ or ‘mild’ can be anything but misleading.

**More consumer information**

Banning misleading descriptors will reduce the amount of erroneous information consumers receive but further information is also needed to assist smokers in understanding the toxicity of cigarettes and other tobacco products.

Smokers are confused about the health risks of different ingredients in cigarettes and the HEA report suggested giving further information about tar and nicotine and about compensatory smoking.

The EU directive leaves Member States to decide whether and what amount of information on additives and ingredients should be made public. It is important that Member States make all the information they receive on cigarettes available to the public although they will need to communicate this information so that it is accessible and meaningful. The Massachusetts 1996 Disclosure Act requires companies to disclose to the public the ingredients added to each brand of cigarettes, snuff and chewing tobacco to enable consumers to make informed decisions about the products. A recent ruling by the US Court of Appeals upheld this legislation following challenges by the tobacco industry.
Annex 1,
Recommendations of the Oslo conference

1. All countries need to introduce comprehensive tobacco control policies and strategies along the lines recommended by the World Health Organization.
   These should be adequately financed and managed by institutions with a clear mandate for tobacco control. The emphases of policies should be to prevent initiation, increase the quit rate, and eliminate exposure to passive smoking. Within the context of a comprehensive policy, product regulation should be given explicit and urgent attention in order to reduce the health impact of tobacco use among smokers. Product regulation needs to apply to all forms of tobacco and nicotine products.

2. Governments are urged, individually or at a regional level, to take the following actions:
   - Evaluate and implement the most effective ways to achieve a unified regulatory framework for nicotine delivery products, including tobacco products, products for treating tobacco dependence, and novel nicotine delivery devices, whether or not these are based on tobacco products. Key terms of reference are to:
     - Maintain a primary focus on harm reduction
     - Develop better measurement of the constituents and impact of tobacco products with the aim of substantially reducing their toxicity
     - Promote international comparability
     - Implement a pre-market approval and post marketing surveillance system.
     - Ban the use of misleading terms such as “light”, “mild”, and other words or imagery (including certain brand names) which have the aim or effect of implying a reduced health risk attributable to low tar or nicotine measurements on tobacco products and in advertising/promotional material.
     - Remove tar and nicotine measures derived from ISO/FTC methods from packages. Warning labels should emphasize the addictiveness of tobacco products.
     - Require tobacco manufacturers to disclose the contents, purpose and effects of constituents in all their products at regular intervals.
     - Discontinue harm reduction strategies based on naive interpretation of tar and nicotine yield measurements. This means abandoning the strategy of seeking lower nominal tar yields and instead, finding approaches that genuinely reduce harm to nicotine users.
     - Give urgent priority to studying the implications for harm reduction of
reducing levels of nicotine and other possible addictive constituents in tobacco products over time.

- Give greater attention to increasing public access to the range of effective methods of treating tobacco dependence, including nicotine replacement therapies (NRTs), and to encourage development and marketing of additional effective products.
- Develop and implement a comprehensive long-term communication program to accompany all the above actions that stresses that there is no safe cigarette and that nicotine addiction is a major public health concern.

3. **Research is needed to advance further progress.**
- Global tobacco control research needs to be better supported. Within such a plan, emphasis should be given to research to support product regulation within developing countries. Existing research institutions should work together to implement such an approach.
- In order to reduce the addictiveness of tobacco products, research is urgently needed to evaluate the benefits and/or hazards of reducing nicotine and other possible addictive constituents in tobacco products over time. Particular attention should be given in research to determining whether a threshold exists for addictiveness.
- Develop better measures, including biomarkers, to assess the health impact of the use of “less harmful” tobacco products in order to drive future regulatory actions. For exposure, a composite measure of toxicity is needed. In addition the unintended consequences of such products should be investigated.
- Expand behavioural research on how “cigarettes affect smokers” and how the population (of smokers and nonsmokers) responds to claims about new products and to new packaging rules.
- Determine whether regulators should encourage the development of substantially less harmful nicotine delivery devices.
- Determine whether countries should forbid addition of all new additives and explicitly address the possibility of reducing the use of additives that make tobacco products more attractive and/or taste better.
- Evaluate how regulatory approaches developed for cigarettes could be adapted to cover all forms of tobacco use.

4. **International collaboration**
- Establish under WHO authority, an international expert group on tobacco and nicotine delivery devices. It needs to be well financed and have access to the best technical expertise available. It would guide international policy development with respect to product regulation and could facilitate access to scientific information needed for tobacco regulation. Its first task would
be to study the recommendations of the Oslo meeting and recent scientific reports on the topic and make recommendations for action to WHO.

- A global team of experts, facilitated by WHO is needed to help countries deal with industry arguments and development of tobacco product regulations.
- Ensure that issues related to product regulation are incorporated into the Framework Convention for Tobacco Control and related protocols.
- Communicate the outcome of this meeting to all appropriate national, regional and international agencies in an attempt to foster uniform approaches.
Annex 2,

The provisions of Directive 2001/37/EC on the manufacture, presentation and sale of tobacco products

- **Maximum yields:** From 1 January 2004, the yield of cigarettes, marketed or manufactured in the European union shall not be greater than:
  - 10 mg per cigarette for tar;
  - 1 mg per cigarette for nicotine;
  - 10 mg per cigarette for carbon monoxide.

The yields, measured on the basis of International Organization for Standardization (ISO) standards, are to apply to products both manufactured and marketed in the EU. The requirement therefore has implications for exports. The application of this aspect of the Directive to export products has to come into effect between 1 January 2005 and 1 January 2007.

Member States may also require tobacco manufacturers or importers to carry out any other tests in order to assess the yield of other substances produced by their tobacco products on a brand name by brand name basis and type by type basis and in order to assess the effects of those other substances on health, taking into account inter alia their addictiveness.

The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered (12% for two official languages and to 15% for three official languages).

- **Warning labels:** to cover 30% of the front of the pack (32% for two languages and 35% for three languages) and 40% of the back of the pack (45% for two languages and 50% for three languages)

- **Warning texts:** general warning on the front - either ‘Smoking kills (or ‘can kill’, depending upon transposition) or ‘Smoking seriously harms you and those around you’ to be alternated on a regular basis; additional warnings on the back - a list of about twelve different texts, also to be alternated on a regular basis.

The text of warnings and yield indications shall be:

- printed in black Helvetica bold type on a white background.
- in lower-case type, except for the first letter of the message and where required by grammar usage;
• centred in the area in which the text is required to be printed, parallel to the
top edge of the packet;
• surrounded by a black border not less than 3 mm and not more than 4
mm in width which in no way interferes with the text of the warning or
information given;
• in the official language or languages of the Member State where the product
is placed on the market.

• **Use of colour photos and graphics etc:** The Commission has been asked
to prepare rules for the use of colour photos (e.g., as recently introduced
in Canada), graphics etc by December 2002. Member States who wish to
authorise the use of pictures etc. will then be entitled to do so, but only
within the context of the agreed rules.

• **Reporting requirements:** Member States shall require manufacturers and
importers of tobacco products to submit to them a list of all ingredients,
and quantities thereof, used in the manufacture of those tobacco products
by brand name and type. This list shall be accompanied by a statement
setting out the reasons for the inclusion of such ingredients in those tobacco
products. It shall indicate their function and category. The list shall also
be accompanied by the toxicological data available to the manufacturer or
importer regarding these ingredients in burnt or unburnt form as appropri-
ate, referring in particular to their effects on health and taking into account
inter alia any addictive effects.

The required information shall be provided on a yearly basis and for the first
time by 31 December 2002 at the latest. The requirement is qualified by refer-
ce to trade secrecy, although it then seems to be up to individual Member
States to decide how much of this information they make public.

The Directive defines ingredient in the following way: **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.

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 prod-
ucts, taking into account inter alia their addictiveness.

• **Misleading descriptors:** The use on tobacco product packaging of certain
texts, such as “low-tar”, “light”, “ultra-light”, “mild”, names, pictures and
figurative or other signs, may mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption. With effect from 30 September 2003, texts, names, trademarks 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 smokers’ perception of these terms may be influenced by linguistic and other factors and may vary from country to country. It is the responsibility of the Member States to draw up the list of forbidden terms.

- **Traceability**: batch numbers, or their equivalent, will have to be applied to each individual carton to ensure that the date and place of manufacture can be determined. This is designed to ensure that all tobacco products, which Member States are entitled to test in order to ensure that they comply with the requirements of the Directive, can be traced back to source and, if necessary, recalled.

- **Monitoring and review**: Mechanisms will be introduced to ensure that the implementation of the Directive is properly monitored and that the provisions of the Directive are kept up-to-date in terms of scientific developments. The Commission shall be assisted by a committee in order to adapt to scientific and technical progress:
  - the maximum yield measurement methods and the definitions relating thereto;
  - the health warnings and the frequency of rotation of the health warnings.
  - the marking for identification and tracing purposes of tobacco products.

No later than 31 December 2004, and every two years thereafter, the Commission shall submit a report on the application of this Directive.

With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available. On submission of the first report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:

- subsequent reduction of the tar, nicotine and carbon monoxide maximum yields,
• possible links between these yields,

• improvements in health warnings, in terms of size, position and wording,

• new scientific and technical information regarding labelling and the printing on cigarette packets of photographs or other illustrations to depict and explain the health consequences of smoking,

• methodologies for more realistically assessing and regulating toxic exposure and harm,

• evaluation of the addictive effects of those ingredients which encourage addiction,

• evaluation of tobacco products which may have the potential to reduce harm,

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

• 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,

• development of standards concerning products other than cigarettes, in particular rolling tobacco.
References


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Findings of the international Expert panel on cigarette descriptors, convened by the Canadian Ministerial Advisory Council on Tobacco Control, Hull, Quebec, 27-28 August 2001.


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The cigarette is the only consumer product that kills when used as intended by its manufacturers. It is a highly engineered delivery system for the drug nicotine, yet compared to food and pharmaceuticals it’s content, yield and delivery are virtually unregulated. A comprehensive tobacco control strategy should therefore include a framework within which tobacco can be appropriately regulated.

The World Health Organization Regional Office for Europe held a conference on the regulation of tobacco products in Helsinki in 1999. The purpose of the conference was to identify the most appropriate regulatory actions that need to be considered as part of comprehensive efforts to reduce smoking attributable death and disease and to suggest regulatory changes that could lead to improved public health, (conclusions of this conference are available from the WHO Regional Office for Europe).

Since the Helsinki Conference, several important developments have occurred. The WHO has established an international advisory committee on tobacco product regulation, negotiations are underway on the Framework Convention on Tobacco Control including proposals for tobacco product regulation, and the European Parliament and the Council have adopted Directive 2001/37/EC on the regulation of tobacco products. This report “Regulation of Tobacco Products: An Update on European Developments 1999-2001” discusses these developments and makes some recommendations for regulation of tobacco products in the future.

For further information please contact

Tobacco free Initiative
WHO Regional Office for Europe
Scherfigsvej 8
DK-2100 Copenhagen
Denmark

Telephone + 45 39 17 17 17
Telefax +45 3917 1718
Telex 12000 who.dk
http://www.who.dk/tobacco/home.html