

**Consultation on the Tobacco Products Manufacture, Presentation and Sale
(Safety) Regulations 2002**

implementing

**Directive 2001/37/EC of the European Parliament and the Council
concerning the Manufacture, Presentation and Sale of Tobacco Products**

This document invites comments on the draft Regulations to implement EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products. Please send your comments to the address below before **23 September 2002**.

Contact point:

Alexandra Norrish,
CVD and Cancer Prevention Policy,
Department of Health,
Room 646, Wellington House,
133-155 Waterloo Rd,
London.
SE1 8UG

Tel: 020 7972 1397

Fax: 020 7972 4965

Email: labelling-directive@doh.gsi.gov.uk

Please note that all responses to this consultation may be made public unless you request that your response be kept confidential.

CONTENTS

Regulatory Impact Assessment on the implementation of Directive 2001/37/EC	
<i>The issue</i>	2
<i>Background</i>	2
<i>Timing</i>	3
<i>Risks</i>	4
<i>Benefits</i>	6
<i>Compliance costs for consumers and business</i>	10
<i>Summary and recommendation</i>	18
Appendix 1: Summary table of costs and benefits of the implementation of Directive 2001/37/EC	19
Appendix 2: Draft regulations to implement Directive 2001/37/EC	20
Appendix 3: Text of Directive 2001/37/EC	33

Regulatory Impact Assessment on the implementation of EU Directive 2002/37/EC

The issue

1. On 18th July 2001 the European Parliament and Council published the text of EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products (the Labelling Directive). The proposals, when adopted into UK law, will define the maximum tar, nicotine and carbon monoxide yields of cigarettes, lay down new requirements for the labelling of the contents of cigarettes, and increase the size of the health warnings used on packs of cigarettes and other tobacco products.
2. There are still substantial differences between different Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco products. These differences impede the working of the internal market. The Labelling Directive is intended to eliminate them by approximating Member States' laws on these issues. For this reason the Directive has been based in particular on Articles 95 and 133 of the Treaty establishing the European Community, regarding the workings of the internal market. In addition, in accordance with Article 95(3) of the Treaty, the Directive takes as a basis a high level of health protection.
3. A copy of the proposed Regulations to translate the Directive into UK law is attached at Appendix 2, and a copy of the Directive itself at Appendix 3.

Background

4. In 1989 the EU adopted regulations on the labelling of tobacco products and the prohibition of marketing of certain types of oral tobacco (89/622/EEC), and in 1990 a further Directive was passed placing limits on the tar yields of cigarettes (90/239/EEC). These regulations were amended in 1992 (Directive 92/41/EEC). The new Labelling Directive is intended to draw together, update and augment existing legislation in the light of the latest scientific and medical evidence. The Labelling Directive (2001/37/EC) was published on 18th July 2001.
5. Within the UK, one public consultation has already been held on the Labelling Directive. In July 2001 the Department of Health consulted widely on the derogation for the application of the new regulations on tar and other limits to cigarettes intended for export (Article 3). Following the consultation the Secretary of State took the decision to implement the maximum possible derogation for cigarettes intended for export.
6. In addition to the formal public consultation, the Department of Health has consulted widely with interest groups and industry during the development of the Directive, and industry has been kept apprised of the likely requirements of the regulations. The Tobacco Manufacturers' Association (TMA) was alerted during the summer of 2001 to the UK's views on the implementation of the Directive, including Article 3 (exports) and Article 5 (labelling).

7. The Labelling Directive is currently subject to a number of legal challenges in the European courts. This consultation is issued without prejudice to any rulings issued by the courts (see in particular paragraphs 45 and 50 below).

Timing

8. Consultation on the Regulatory Impact Assessment and the draft Regulations for the Labelling Directive will run **from 1 July 2002**. Responses must reach the Department of Health **before 23 September 2002**. The consultation period will be 12 weeks, in line with Cabinet Office best practice guidelines.
9. All organisations with an interest in this issue are invited to submit their responses on this consultation document. Responses should be sent to:

Alexandra Norrish
Department of Health
Room 646, Wellington House
133-155 Waterloo Rd,
LONDON SE1 8UG

Tel: 020 7972 1397
Fax: 020 7972 4965

email: labelling-directive@doh.gsi.gov.uk

10. Following analysis of the consultation responses, regulations will be laid before Parliament during Autumn 2002. In line with Cabinet Office guidance 12 weeks will be allowed for implementation between the end of the Consultation and the Directive coming into force, so the Directive will become UK law on **16 December 2002**. (The deadline laid down in the Directive is 30 September 2002, but in order to comply with Cabinet Office guidelines on implementation times this has been slightly delayed.) The measures contained within the Directive will be phased in as follows:

- ◆ **Labelling requirements and health warnings:** Non-compliant cigarettes may be manufactured until 16 December 2002 and marketed until 30 September 2003. Non-compliant cigars and other tobacco products may be manufactured until 16 December 2002 and marketed until 30 September 2004.
- ◆ **Product descriptions:** Non-compliant tobacco products may be manufactured and marketed until 30 September 2003.
- ◆ **Yields:** Non-compliant products may be manufactured and marketed until 1 January 2004. Non-compliant products intended for export may be manufactured and marketed until 1 January 2007.

Risks

11. Tobacco is a uniquely dangerous consumer product. Smoking is the greatest single cause of preventable illness and premature death in the UK, killing up to 120,000 people a year in the UK.^a It is estimated that treating smoking-related diseases costs the NHS up to £1.7 billion every year.^b Half of all those people who continue to smoke for most of their lives will die of the habit, half of these before the age of 69,^c while 30% of all cancer deaths and 84% of the deaths from lung cancer in the UK are caused by smoking.^d One out of every 7 deaths from heart disease is caused by smoking.^e
12. In 2000 27% of adults in England smoked.^f Worryingly, in the same year, 10% of young people aged 11-15 admitted to smoking regularly.^g
13. A complex range of factors contribute to encouraging people to smoke, particularly young people. However, research has shown that two reasons for the prevalence of smoking amongst young people are a common belief that the health effects of smoking are long-term and irrelevant to them; and a lack of awareness of the addictive nature of nicotine.^h The health warnings proposed under the Labelling Directive are intended to redress this.
14. The addictive properties of nicotine make it extremely hard for smokers to give up altogether. Some smokers compromise by choosing to smoke instead varieties of cigarette which they believe will be less harmful to their health.ⁱ Chief amongst these are 'light' or 'mild' varieties of cigarettes, which are widely believed to be 'safer' than normal cigarettes, in that they 'contain' less tar and nicotine. However, the tar and nicotine content of the tobacco in a 'light' or 'mild' cigarette is frequently no lower - or may even be higher - than that in a normal cigarette. When the tar and nicotine yield from a 'light' cigarette is measured by a machine, it is indeed lower than that of a standard cigarette. However, this fall in the yield is caused almost entirely by the structure of the cigarette, for example the number of air holes in the filter used, rather than by a difference in the actual tar and nicotine content of the tobacco.^j The different structure of the filter is effective when a 'light' cigarette is smoked only by a machine, but there is compelling evidence that smokers will unconsciously compensate for the effect of the filters and other mechanisms used in 'light' cigarettes by smoking each cigarette more intensively, with the consequence that they in fact extract the same or

^a Callum C, *The UK smoking epidemic: deaths in 1995*. London: Health Education Authority, 1998.

^b Buck D, Godfrey C et al, University of York Centre for Health Economics, *Cost effectiveness of smoking cessation interventions*. London: Health Education Authority, 1997.

^c Petro R., Lopez AD, Boreham J. et al, Imperial Cancer Research Fund and World Health Organisation, *Mortality from smoking in developing countries 1950-2000*. Oxford: Oxford University Press, 1994.

^d Callum C, *The UK smoking epidemic*.

^e *ibid.*

^f Office of National Statistics, *Living in Britain: results from the 2000 General Household Survey*. London: Office of National Statistics, 2001.

^g Department of Health, *Smoking, drinking and drug use among young people in England in 2000*. London: Department of Health, 2001.

^h See particularly the World Bank Report, *Curbing the Epidemic: Governments and the Economics of Tobacco Control*. Washington: The World Bank, 1999 p. 5, p 31.

ⁱ National Cancer Institute Expert Committee, *The FTC cigarette test method for determining tar, nicotine and carbon monoxide yields of US cigarettes*. NIH Publication No 96-4028. Smoking and Tobacco Control Monograph No. 7, Washington DC: NCI, 1996.

^j Kozlowski LT, Mehta NY, Sweeney CT, Schwartz SS et al, *Filter ventilation and nicotine content of cigarettes from Canada, the United Kingdom, and the United States*. *Tobacco Control* 1998; 7:296-375.

nearly the same levels of nicotine and tar from a 'light' cigarette as from a standard variety.^k It is for this reason that the Directive proposes a ban on misleading descriptors such as 'light' and 'mild'.

^k eg Stephen A, Frost C, Thompson S, Wald N, Estimating the extent of compensatory smoking, in Wald N, Froggatt P (eds), *Nicotine, smoking and the low tar programme*. Oxford: OUP, 1989 pp. 100-115.

Benefits

Effect on tobacco consumption

15. There is evidence from around the world that the presence of health warnings both deters non-smokers from starting, and encourages existing smokers to give up.¹ In its report *Curbing the Epidemic* the World Bank recommended the use of prominent health warnings as an effective tool to combat smoking, even in countries which already have a long tradition of health education in the harmful effects of tobacco.^m It is hard to quantify precisely how large the effect of such health warnings may be in reducing the number of people who smoke in this country. However the Directive is likely to go some way towards helping us to meet the targets which the Government set in its White Paper *Smoking Kills* (no more than 26% of the adult population to smoke by 2005 and 24% by 2010). A realistic figure may be that new health warnings will eventually lead to between a 0.5% and a 1.0% reduction in the number of smokers.ⁿ The health effects of smoking cessation are long-term, but this fall in the number of smokers could ultimately save between 600 and 1200 of the 120,000 lives lost to smoking-related diseases every year in the UK.

Public awareness

16. Raising public awareness of the risks involved in smoking is essential in enabling people to make an informed choice about whether or not to smoke. The Directive will make a significant contribution to informing both smokers and non-smokers about the very real dangers of smoking. The new health warnings, designed to take up a larger surface area of the pack than current warnings, and to be more prominent (printed in black and white), will convey clear and accurate information about the health risks involved in smoking. Statements such as ‘Smoking clogs the arteries and causes heart attacks and strokes,’ ‘Smoking causes fatal lung cancer,’ and ‘Smokers die younger’ give clear information about the possible consequences of smoking. In addition, several of the warnings are targeted to be particularly relevant to the concerns of young people, for example ‘Smoking may reduce the blood flow and causes impotence’ and ‘Smoking is highly addictive, don’t start.’
17. Equally importantly, the Directive aims to combat the misleading information about cigarettes and smoking that is circulated by the tobacco industry. It will do this particularly by banning the use of ‘misleading descriptors’ such as ‘light’ and ‘mild’. Such terms are, as discussed above, misleading in the suggestion that light cigarettes are invariably ‘safer’ in that they will provide all smokers with a lower yield of tar or nicotine

¹ See particularly the review by the Australian Commonwealth Department of Health and Aged Care, *Review of Health Warnings on Tobacco Products in Australia*. Canberra: Commonwealth Department of Health and Aged Care, 2001, publication no. 2858 p. 7.

^m ‘It has sometimes been argued that, in the more informed populations where smoking has been widespread for many decades, smoking prevalence is unlikely to fall much lower than it has already as a result of cigarette pack warning labels. However, evidence from Australia, Canada and Poland suggests that such labels can still be effective, provided that they are large, prominent and contain hard-hitting and specific factual information.’ *Curbing the Epidemic* p. 47.

ⁿ This figure is calculated in relation to the reduction in the number of smokers which is anticipated as a result of a ban on advertising in the UK. The advertising ban is predicted to produce a 2.5% reduction; it is estimated that the less direct impact of health warnings will generate a reduction between one fifth and two fifths of that achieved by the advertising ban.

than a normal cigarette. The Royal College of Physicians suggests that ‘smokers of low yield cigarettes actually achieve little, if any, reduction in intake of nicotine and tar’.^o The banning of misleading descriptors will ensure that the many smokers who change to a ‘light’ brand rather than giving up smoking altogether will no longer be misled into believing that they are protecting their health.

18. As well as the general information contained in the health warnings, the Directive will give the public general access to information about the yields of cigarettes. Information about the tar, nicotine and carbon monoxide yields of cigarettes will be displayed on every packet. These yields, being machine measured, may themselves not be entirely indicative of the levels of nicotine and tar that will be inhaled by individual smokers. For this reason the Directive contains a commitment to updating measurement methods in the light of emerging scientific evidence.
19. In addition, the Directive will ensure that a list of all the ingredients used in the manufacture of tobacco products is made available to the public, thus ensuring that smokers are better informed about the other products which they are exposed to while smoking.

Public health protection

20. As well as ensuring that both smokers and non-smokers are informed of the consequences of smoking, the Directive attempts to minimise these consequences. There is no such thing as a safe cigarette. However the Directive lays out limits to the tar, nicotine and carbon monoxide yields of cigarettes (10 mg of tar, 1 mg of nicotine, and 10 mg of carbon monoxide per cigarette). The Directive also gives the Commission scope to propose a list of ingredients permitted for use in the manufacture of tobacco products.
21. For the reasons outlined above there is some controversy over whether reducing the levels of nicotine and tar contained in each cigarette will have major health benefits, as machine-measured yields of tar, nicotine and carbon monoxide may not always be indicative of the levels that a smoker actually inhales. However this regulation is a step towards attempting to reduce the harm done by the levels of nicotine, tar and carbon monoxide in individual cigarettes. There are arguments to suggest that regulating the tar to nicotine ratio of cigarettes is more effective than placing a simple limit on the tar and nicotine yields. For this reason the Directive makes provision for its requirements to be updated regularly, in light of the latest scientific and public health information, and contains a Commission commitment to review the issue of yields in its first report on the application of the Directive.
22. The same restrictions on yields as apply to cigarettes sold within the UK will also apply to cigarettes exported from the UK to outside the EU. The UK has chosen to apply the maximum possible derogation on this (until 1 January 2007) in order to give the industry time to adjust its production processes.

^o Royal College of Physicians, *Nicotine Addiction in Britain: a report of the Tobacco Advisory Group of the Royal College of Physicians*. London: Royal College of Physicians, 2000.

Health benefits for smokers and non-smokers

23. It is hoped that the wider information on the consequences of smoking and the benefits of quitting made available through health warnings will lead more people to quit, while deterring non-smokers from starting. There is ample evidence not only that non-smokers enjoy a healthier and longer life than smokers, but also that quitters do eventually achieve almost the same levels of health as people who have never smoked.^p
24. Several provisions in the Directive (such as the specifically-targeted health warnings) are aimed particularly at preventing young people from starting smoking or encouraging them to stop. The health benefits from preventing young people are particularly great, as this may pre-empt a lifetime of ill-health associated with smoking.

The NHS

25. It is estimated that treating smoking-related diseases costs the NHS up to £1.7 billion every year. If, for example, 0.5% to 1% of smokers were encouraged to quit by the new health warnings, the NHS could ultimately save £8.5m to £17m p.a.. (As noted above, the health effects of smoking cessation are long-term and this benefit would be felt gradually.)

Business

26. Smoking in the workplace can have a serious impact on productivity, through reducing the effectiveness of workers, losing time associated with smoking breaks, and increasing sickness absence. Studies by the US Government suggest that improving air quality by banning smoking gave rise to a productivity gain of 3%.^q Smoking breaks can have a serious impact on productivity: one study suggested that the average smoker takes 5 cigarette breaks lasting 6 minutes each day, a loss of 30 minutes per day or two and a half hours per week due to smoking. One Scottish study used this figure and other research to calculate that lost productivity due to smoking was costing employers more than £450m per annum; the cost for England would be of the order of 10 times higher.^r A 0.5% to 1% fall in the number of smokers could save business £22.5m - £45m.

^pThe benefits of quitting are immediate: after only 72 hours breathing becomes easier; after 3-9 months lung function improves by 5 - 10%; after 5 years the risk of a heart attack falls to half that of a smoker; and after 10 years the risk of lung cancer falls to half that of a smoker, while the risk of a heart attack falls to the same as someone who has never smoked. QUIT, *Helping smokers to quit*. London: QUIT, 1994, updated 1996.

^q United States Occupational Safety and Health Administration, *Indoor Air Quality*, May 1994.

^r Parrot et al, Costs of employee smoking in the workplace in Scotland, *Tobacco Control*, 2000:9 pp. 187-192.

Trade

27. The intention of the Directive is to ensure an equal footing for trading within the EU, and to promote the functioning of the Single Market. The requirement laid on all Member States to introduce the same specifications for product content and labelling (subject to the limited matters left to the discretion of Member States) will ensure that the labelling and composition of tobacco products present no barrier to trade in the EU.

Compliance costs for consumers and business

General issues

28. In 2000, UK consumers spent £15.1bn on tobacco related products.^s This represents a substantial profit for the tobacco industry, as well as, through taxation, £9.6bn of total revenue for the Government.^t However, this apparently high revenue must be weighed not only against the £1.7bn in costs to the NHS, and the massive personal cost to both smokers and those non-smokers (including children) who are exposed to tobacco smoke, but the direct and indirect costs that smoking places on business in the form of lost productivity.
29. The implementation of the Directive will carry a number of short-term costs, most of which will be borne by the industry. The UK Government has attempted wherever possible to reduce the compliance costs involved in implementing the new regulations, for example by informing the industry of new requirements at an early stage, and seeking the maximum derogation on several issues to give time to phase in new equipment.
30. In line with Regulatory Impact Assessment guidelines and the Scottish Parliament's requirements for information, this section tries to identify the direct costs of the Directive to particular groups.

Manufacturers

31. As far as UK companies are concerned the compliance costs of the Directive will fall overwhelmingly on the large UK tobacco companies, BAT, Rothmans (now part of the BAT group), Gallaher and Imperial Tobacco. All three are extremely large tobacco companies with interests overseas as well as the UK.
32. The majority of cigarette imports into the UK are made by the UK manufacturers themselves. Independent importers, i.e. those who only import cigarettes and do not manufacture in the UK, are few in number and range from medium sized enterprises to small entrepreneurs. Some small specialist manufacturers and importers, dealing in tobacco products other than cigarettes, will also be affected by the requirements of the Directive.

Reducing yields

33. The Tobacco Manufacturers' Association (TMA) estimates that 62% of UK production of cigarettes exceeds the ceilings on either tar, carbon monoxide or nicotine.

^s £15,146m at current prices (£11,184m at constant 1995 prices) (codes CCDZ and CCBP). ONS, *Consumer Trends*, Quarter 2 2001 (tables 4.1 and 4.13).

^t Tobacco duty and VAT on related expenditure.

34. The majority of cigarettes marketed in the UK already comply with the tar and nicotine levels laid out in the new Directive, so reducing tar and setting a ceiling on nicotine would not have significant costs. The main costs in this area will relate to consumer testing of changes.
35. However, the TMA has estimated that reducing carbon monoxide to a maximum of 10 mg will, in their view, cost the three major manufacturers over £2m p.a. each on materials and related product efficiency (ie £6m for all three). ASH argue that the technology for selective control of carbon monoxide already exists, and that the use of such technology will have incidental benefits in removing other semi-volatile toxins within cigarette smoke.

Labelling

36. The new labelling requirements will cost the major UK manufacturers around £3m each to introduce. This will cover the design of new artwork, and the printing of new materials (blanks, wrappers and cases). The costs for manufacturers of cigars and pipe tobacco, though smaller because businesses tend to be smaller, may be more significant, given the small (and falling) market share which these occupy compared with cigarettes. It is possible that, given the wide range of pressures currently on the UK cigar and pipe tobacco markets, this could contribute to some closures and a reduction in the range of products available.
37. Production of non-compliant packaging must cease by 16 December 2002. (The deadline in the Directive is 30 September 2002, but this has been slightly delayed in order to comply with Cabinet Office guidelines on implementation times.) The TMA was alerted during the summer of 2001 to the UK Government's requirements on labelling, in order to permit adequate time for the necessary changes to the design of packaging and to the printing machinery. In particular, the TMA were informed of which text the Government has decided to implement for the health warnings. They were also alerted to the Government's view, based on advice from the European Commission, that the 3-4mm black border that surrounds the health warning should be outside the area of the surface (for cigarette packets, 30% of the most visible surface and 40% of the next most visible surface) set aside for the text of the health warning. This early notice was intended to ensure that the manufacturing and packaging industries were able to meet the deadline.
38. A lead-in time of one year has been allowed for the marketing of non-compliant packaging produced before that date: non-compliant product may be marketed until 30 September 2003 (30 September 2004 for tobacco products other than cigarettes). This is designed to reduce wastage, by allowing manufacturers and retailers to use up existing stocks of non-compliant packaging before the implementation date.

Measurement of contents

39. Measuring yields of tar, nicotine and carbon monoxide should incur minimal additional costs for the manufacturers, as they have the equipment to measure this information already. The machinery used to read carbon monoxide yields is the same as that used to measure tar and nicotine levels, which the manufacturers are already required to provide to the Government on a regular basis.
40. In addition to the basic provisions on the testing of tar, nicotine and carbon monoxide yields, the Directive also gives Member States the power to require manufacturers or importers to test the yields of other substances produced by their tobacco products. The TMA has argued that allowing Member States to introduce whatever tests they want has potentially huge financial consequences. Realistically however there is unlikely to be a huge demand for additional testing in the short term, as the laboratory capacity for such testing is limited.
41. In addition to requiring manufacturers to test the yields of substances other than tar, nicotine and carbon monoxide, the Directive also requires manufacturers to supply the Government annually with a list of all ingredients used in the manufacture of their products, by brand name. The requirements for submitting this information have been arranged to dovetail with current requirements for submitting information on additives.

Sales

42. It is expected that the Directive, and particularly its new requirements on health warnings, will have the long-term effect of reducing the number of smokers in this country. For this reason the level of sales of cigarettes in the UK may fall. Such a fall is extremely difficult to quantify; for the purposes of this assessment a 0.5% - 1.0% reduction in the number of smokers is suggested, with an equivalent fall in sales.
43. If expenditure on tobacco products fell by around 0.5% - 1.0%, this would represent a fall in expenditure of £75.5m - £151m at 2000 prices. This would probably not represent a loss to the economy overall, as it is likely that this sum would be spent on other goods and services.
44. The loss of revenue for the industry would probably be spread across brands, though certain brands might be expected to suffer more than others. Under the Directive, trade marks which include descriptors which may mislead the consumer into the belief that some products are less harmful than others (such as 'mild' and 'light') will be banned. This ban will require some brands or varieties of cigarette to change their names. Those brands or varieties which are required to change their names (just over 20% of the UK cigarette market, based on current products and market share) may suffer a greater fall in sales than those not affected by the requirement.

Exports

45. The application of the Labelling Directive to products for exports to countries outside the European Union is currently under consideration in the European courts. This consultation is issued without prejudice to any ruling provided by the courts.
46. There is a small chance that the application of the new requirements of the Labelling Directive to cigarettes destined for the export market could cause tobacco companies to move their custom to factories outside the EU, where the regulations would not apply. The relevant Articles of the Directive are those dealing with the limits on yields of tar, nicotine and carbon monoxide, and those dealing with a ban on descriptors which give the impression that one tobacco product is less harmful to health than others.
47. The application of the ban on descriptors to cigarettes intended for export is one of the most controversial aspects of the Directive. The TMA and the ECF (European Committee of Food, Catering and Allied Workers' Unions) have argued that the application of the Directive's requirements on yields and descriptors to this export trade endangers the revenue and the employment generated in the UK by the export industry. At present 75% of cigarettes manufactured in the UK are exported, 74% of which go to non-EU countries.^u Cigarette exports in 2000 accounted for £889m (£529m to non-EU countries^v).
48. A proportion of these exports, both to EU and non-EU countries, will be banned under the Directive, either because they provide too high a yield of tar, nicotine or carbon monoxide, or because they make use of descriptors banned by the Directive. The exact percentage of exports that will be affected is unknown: according to the TMA 62 % of cigarettes currently manufactured in the UK are non-compliant with the Directive; it is possible that the proportion of non-compliant cigarettes intended for export is higher than the proportion of non-compliant cigarettes manufactured in the UK as a whole. However, it is likely that a majority of non-compliant cigarettes would require only very slight changes to make them compliant. If 62% of the exports were non-compliant and could not be altered to make them compliant, £551.8m worth of exports would be banned. It is highly unlikely that the effect would be this severe.
49. The TMA suggest that the new requirements may cause tobacco manufacturers to move production out of the UK, and possibly outside of the EU. However the requirements on yields is unlikely to be a major factor in influencing the industry's decisions. In the case of the restriction on yields, UK-manufactured products have a high reputation as premium products abroad, and already compete successfully with higher-tar products outside the EU. Any movement of production to outside the EU is likely to be part of an ongoing trend rather than a response specifically to the Labelling Directive. There is evidence that tobacco manufacturers are already reducing the number of people employed in tobacco production in the UK: numbers have fallen from 9,600 in 1998 to 7,106 in 2001,^w or by 26% over 3 years. We are aware that there is global over-capacity in tobacco manufacturing and companies are already taking long-term decisions to re-source production to countries which appear to offer a more advantageous trading environment.

^u Office of National Statistics, *Product Sales and Trade - PRA 16000 - Tobacco Products 2000*. ONS: London 2001

^v *ibid.*

^w As at 1st September 2001. Figure supplied by the Tobacco Manufacturers Association.

This suggests that manufacturers are already involved in reducing their workforce in the UK, and these decisions are likely to be taken with or without the new Directive's provisions on exports.

50. The ban on product descriptors under Article 7 will take effect from 30 September 2003 both for products intended for sale in the EU and for those intended for export (if the European Court of Justice rules that Article 7 applies to exports). However the new requirements under Article 3 (yields of tar, nicotine and carbon monoxide) will not take effect on cigarettes for export until 1 January 2007. By this date the WHO's Framework Convention on Tobacco Control is due to have been signed. The FCTC is likely to include requirements on maximum yields and on descriptors; these would apply to all signatories of the WHO Convention and could amount, in effect, to a global requirement on maximum yields as well as a global ban on descriptors such as 'light' and 'mild'. Details of the precise text of the Convention, its implementation dates, and any derogations that it will contain, have yet to be finalised.

Ban on oral tobacco

51. Oral tobacco is defined as all tobacco products which are intended for oral use, except for those products intended to be smoked or chewed. Usually it comes in the form of powder or grains. Like all tobacco products, oral tobacco carries a health risk for its users, and the sale of oral tobacco has been banned in the UK for the last 10 years under UK's Tobacco for Oral Use (Safety) Regulations 1992 which implemented the relevant part of Council Directive 92/41/EEC. Article 8 of the 2001 Labelling Directive also bans oral tobacco. The 1992 Regulations have not been revoked, and the 1992 Regulations thus fulfil the requirements for a ban contained in the 2001 Labelling Directive.
52. The ban contained in the 1992 Regulations refers only to the sale of oral tobacco. Therefore it is still possible for oral tobacco to be manufactured in the UK for export to EU or EEA countries exempt from the ban, or to countries outside the EU. Under the terms of the Directive, any oral tobacco manufactured for export in this way in the UK would be liable to the same controls as apply to other tobacco products manufactured in the UK for export. It is expected that, as this is a very small market, any costs arising from this will be minimal.

Packaging Industry

53. The major cost of redesigning packaging in line with the new labelling requirements, in particular the new health warnings and the new lists of contents, will be borne by the packaging industry. There are two major printing companies in the UK which hold the majority of the marketshare for supplying packaging to the tobacco industry.
54. The printing companies will have to meet the costs of the manufacture of new embossing tools and print cylinders. In the case of cigarettes, cigars and pipe tobacco the cylinders will need to be redesigned to incorporate 2 general warnings and 14 additional warnings, which must be rotated so as to guarantee their regular appearance; in the case of oral tobacco and smokeless products the cylinders will need to be redesigned to incorporate one general warning.

55. Each print cylinder will cost approximately £1,000 to replace; the two largest companies currently use 4 - 5,000 separate cylinders, and may need up to 1,000 more new cylinders to accommodate the requirements for the rotation of health warnings on outside packaging. The cost of replacing all cylinders, for the two largest companies, can thus be seen to be in the region of £4m to £6m each (£8m to £12m overall). In practice costs will be substantially less than this, as printing cylinders have a normal lifespan of one million revolutions. Depending on the type of ink used and the volume printed, this can give a cylinder a lifespan of anything between 4 months and a year. Industry was alerted in summer 2001 to the new requirements on health warnings, in order to allow time for the changeover of machinery to take place and to allow print cylinders to be replaced gradually.
56. In addition printers will bear costs for the manufacture of new embossing tools, which can cost up to £20,000 each. A large printing company may house anything up to 30-40 embossing tools, which will need to be replaced when the packages are redesigned, at a cost of £600,000 - £800,000 for each of the two main companies (£1.2m to £1.6m in total).
57. Steps have been taken to minimise the cost of the new requirements. The Directive allows a run-in time after the implementation of the Regulations, during which non-compliant packaging may still be sold. For other tobacco products, which have lower turnover, the run-in time will be two years. This is intended to allow manufacturers to implement the changeover and use up existing stocks.
58. The Government has also agreed to an industry request that additional health warning 10 (which will normally display the phone number of the NHS helpline, or, in Scotland, the Scotland helpline) may carry a generic warning rather than the helpline number on packets intended for the travel retail market. This will be more relevant to cigarettes which will mostly be smoked outside the UK, and will help to reduce industry costs as travel retail packs will be produced identically in most European countries.
59. The Department of Health and Her Majesty's Customs and Excise have worked together to ensure that new HMCE requirements for the fiscal marks to be displayed on all cigarette packets will be implemented at the same time as the new requirements of the Directive. This will ensure that the industry only has to undertake redesign of its printing cylinders once.

Small businesses

60. The Labelling Directive's impact on small businesses will be focused predominantly on retailers and printers. A number of small retailers may be affected; however, the Small Business Service (Cabinet Office) indicate that the major impact of falling sales can probably be met in general stores by diversification. The retailers more likely to be adversely affected by any fall in sales are specialist tobacco retailers. There are around 400 specialist tobacco shops in the UK; the impact on these is difficult to quantify, especially given an ongoing trend of closure amongst tobacco retailers. (Membership of the Tobacco Alliance, which represents independent retailers [including both specialists and non-specialists] who sell tobacco, has declined from 26,000 in January 1997 to 20,466 in January 2002.)

Smokers

61. If compliance with the new regulations were to push prices of cigarettes up, then smokers would also bear the cost. However, if the new health warnings encouraged a smoker to quit, a medium-level smoker (smoking 5 packs a week) could expect to save on average £22.00 a week, or £1,144 a year.^x

Central Government

62. The major cost for central Government is contained in the potential loss of revenue through tax. In 2000 the Government received £9.6bn total revenue from taxation of tobacco products.^y A 0.5% - 1% fall in the number of smokers could lead to an annual fall of £48m - £96m in this revenue.

63. The Government should not incur any new costs from the measurement of tar, nicotine and carbon monoxide yields, as the Department of Health already commissions this information on a bi-monthly basis from the LGC (formerly the Laboratory of the Government Chemist), at a cost of around £388,000 per annum.

64. In addition, Government has a responsibility under the Directive to ensure that the newly-available information on the constituents of tobacco is made public. It will probably be possible to use existing routes, including electronic means, for this. This should therefore incur minimal costs.

65. The provision of expert advice to the Commission, and support for it in drawing up its reports, will be met by existing staff and will not incur extra costs.

Local Government

66. Enforcement and prosecution will generally be the responsibility of Trading Standards Officers in England and Wales and their equivalents in Northern Ireland. In Scotland

^x The average price of a pack of 'premium' cigarettes in 2001 was £4.40.

^y Tobacco duty and VAT on related expenditure.

enforcement will be the responsibility of Trading Standards Officers and prosecution that of the Lord Advocate (through Procurators Fiscal). The duty to enforce the Regulations could impart a burden on Local Authorities (and District Councils in Northern Ireland). It is our expectation that this additional burden would be for a short period of time and we expect that manufacturers would maintain their usual practice of operating within UK law. Although some prosecutions may follow we believe that additional costs will be *de minimis* for any individual enforcement agency.

67. In Scotland, prosecution is the responsibility of the Lord Advocate, and the Crown would therefore bear the cost of any prosecution arising from these legislative measures.

Future costs

68. The Directive makes a commitment to adapting requirements to scientific and technical progress. Therefore, there may in the future be changes to (for example) measurement methods and health warnings that would carry costs for the industry or Government.

Summary and recommendation

69. Appendix 1 summarises the likely costs and benefits of implementation of the EU Labelling Directive. The main cost of the ban lies in the short-term implementation, as the printing industry and manufacturers adjust to new requirements on health warnings and labelling, and the ultimate damage to the tobacco industry as consumption falls. The costs will also be affected by the ongoing effects that the Directive will have on exports, which will be influenced by the ECJ's judgement on the application of Article 7. Weighing this against the high financial costs of smoking and the massive burden of death and disease imposed by tobacco use, we are in no doubt that the potential health benefits of the Directive far outweigh any risk to the industry whose product is responsible for this disease and death.

Appendix 1

Summary table of costs and benefits of the implementation of Directive 2001/37/EC

	Expected costs		Expected benefits		Net effects	
	Initial costs	Ongoing costs p.a.	Initial benefits	Ongoing benefits p.a.	Net initial effects	Net ongoing effects p.a.
Manufacturers						
Reducing yields		£6m				- £6m
Labelling requirements	£9 m				- £9 m	
Fall in sales		£75.5m to £151m				- £75.5m to - £151m
Fall in exports ^z		£0 to £551.8m				£0 to - £551.8m
Printers						
Embossing tools	£1.2m to £1.6m				- £1.2m to - £1.6m	
Replacement of cylinders (worst-case scenario)	£8m to £12m				- £8m to - £12m	
Business						
Increase in productivity				£22.5m to £45m		+ £22.5m to + £45m
Government						
Tax		£48m to £96m				- £48m to - £96m
NHS						
Treatment of smoking-related diseases				£8.5m to £17m		+ £8.5m to + £17m
Citizens						
Lives saved				600 to 1200 lives (in the long term)		+ 600 lives to + 1200 lives
TOTAL	£18.2m to £22.6m	£129.5m to £804.8m		£31m to £62m 600 to 1200 lives	-£8.2m to -£22.6m	- £78.5m to - £742.8m + 600 lives to + 1200 lives

^z This estimate is calculated on two extremes of the possible effects that the implementation of the Labelling Directive could have on exports from the UK. The lowest estimate envisages a scenario in which all manufacturers choose to make all their products compliant with UK legislation, thus enabling them to be manufactured in and exported from the UK. The highest estimate envisages a scenario in which all manufacturers withdraw from the UK the manufacture of all their non-compliant products intended for export, and transfer production to outside the EU. The actual situation is likely to be somewhere between these two extremes.

Appendix 2

Draft regulations to implement Directive 2001/37/EC

STATUTORY INSTRUMENTS

2002 No.

CONSUMER PROTECTION

The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002

<i>Made - - - -</i>	2002
<i>Laid before Parliament</i>	2002
<i>Coming into force in accordance with regulation 1</i>	

ARRANGEMENT OF REGULATIONS

1. Citation and commencement
2. Interpretation
3. Maximum tar, nicotine and carbon monoxide yields of cigarettes
4. Statement of yields on packets of cigarettes
5. Testing of cigarettes, samples and information
6. Procedure for determining yields of tar, nicotine and carbon monoxide
7. Warnings on tobacco products
8. Size of warnings
9. Appearance of warnings and yield statements
10. Product identification markings
11. Product descriptions
12. Provision of further product information
13. Prohibitions on supply of non-compliant tobacco products
14. Enforcement and penalties
15. Revocations
16. Savings and transitional provisions

SCHEDULE Regulation 7

List of additional health warnings

The Secretary of State for Health, in exercise of the powers conferred on him by section 11(1) to (3) of the Consumer Protection Act 1987^(aa), and after consultation, in accordance with section 11(5) of that Act, with organisations appearing to be representative of interests substantially affected by these Regulations and other persons considered appropriate, of the powers conferred by section 2(2) of the European Communities Act 1972^(bb) and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 and shall come into force—
 - (a) for the purposes of regulations 3 and 6(1)(a), —
 - (i) as to cigarettes which are or are to be supplied in the United Kingdom or another EEA State and the manufacture of such cigarettes, on 1st January 2004,
 - (ii) as to cigarettes which are or are to be supplied for export outside the European Economic Area and the manufacture of such cigarettes, on 1st January 2007;
 - (b) for the purposes of regulation 11 on 30th September 2003;
 - (c) for the purposes of regulation 15(1) on 1st January 2004;
 - (d) for all other purposes on 16th December 2002.

Interpretation

2.- (1) In these Regulations—

“1991 Regulations” means the Tobacco Products Labelling (Safety) Regulations 1991^(cc);

“EEA State” means a State which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992^(dd) as adjusted by the Protocol signed at Brussels on 17th March 1995^(ee);

“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;

“ISO4387” means the International Standard entitled Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical cigarette-smoking

^(aa) 1987 c.43.

^(bb) 1972 c.68; *see* S.I.1991/755 designating the Secretary of State for the purposes of that subsection in relation to measures relating to the sale, packaging, labelling and sampling of tobacco products.

^(cc) S.I. 1991/1530, amended by S.I. 1993/1947.

^(dd) OJ No. L1, 3.1.94, p.3.

^(ee) OJ No. L1, 3.1.94, p.572.

machine ISO4387: 2000 third edition published by the International Organisation for Standardisation on 6th April 2000;

“ISO8243” means the International Standard entitled Cigarettes – Sampling ISO8243: 1991 second edition published by the International Organisation for Standardisation on 15th October 1991;

“ISO8454” 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 15th November 1995;

“ISO10315” means the International Standard entitled Cigarettes – Determination of nicotine in smoke condensates – Gas-chromatographic method ISO 10315: 2000 second edition published by the International Organisation for Standardisation on 30th March 2000;

“maximum permitted yield” has the meaning set out in regulation 3(2);

“most visible surface”, in relation to a rectangular cigarette package, means that surface of the packet which is, or is equal in area to, the largest surface and either—

(a) faces a person opening that packet; or

(b) where no surface faces a person opening the packet, carries most prominently the name, trademark or other distinguishing mark of the brand of cigarettes,

and in relation to other packets for tobacco products means the most conspicuous surface;

“nicotine” means nicotinic alkaloids;

“other most visible surface”, in relation to a rectangular cigarette packet means the side opposite to the most visible surface;

“packet”, in a relation to a tobacco product, means any box, package, container, wrapping or other receptacle which contains the product, and in which the product is, or is intended to be, presented for retail supply, excluding any additional transparent outer wrapping which may be discarded on opening and excluding any wrapping of individual cigars or cigarillos, and where any such receptacle is or is to be contained in another receptacle (excluding such outer wrapping), includes each such receptacle;

“producer”, in relation to a tobacco product, means a person who in the course of a business—

(a) manufactures it,

(b) puts a name, trademark or other distinguishing mark on it, by which he holds himself out to be its manufacturer or originator, or

(c) imports it into the United Kingdom,
with a view to the product being supplied for consumption in the United Kingdom; and
“produce” shall be construed accordingly;

“rectangular”, in relation to a packet of cigarettes, denotes a packet having only rectangular surfaces;

“supply”, in relation to a tobacco product, means the supply of, or offer or agreement to supply, the tobacco product or the exposure or possession for supply of the tobacco product;

“tar” means the raw anhydrous nicotine-free condensate of smoke;

“tobacco for oral use” means any product made wholly or partly of tobacco which is—

- (a) intended for oral use, unless it is intended to be smoked or chewed; and
- (b) either—
 - (i) in powder or particulate form or any combination of these forms, whether presented in sachet portions or porous sachets or in any other way, or
 - (ii) presented in a form resembling a food product;

“tobacco product” means a product consisting wholly or partly of tobacco, whether genetically modified or not and intended to be smoked, sniffed, sucked or chewed;

“travel retail sector” means retail outlets at which duty free tobacco products may be purchased only by people who are travelling on journeys to destinations outside the European Community.

(2) In these Regulations—

- (a) any reference to Standard is a reference to that Standard as it has effect on the date on which these Regulations are made (including any amendment to that Standard taking effect on or before that date); and
- (b) where any Standard mentions relevant requirements by reference to another Standard, that reference is to be construed for the purposes of these Regulations as a reference to that other Standard as it has effect on the date on which these Regulations are made (including any amendment to that other Standard taking effect on or before that date).

Maximum tar, nicotine and carbon monoxide yields of cigarettes

3. - (1) No person shall manufacture or supply any cigarette the yield of which exceeds the maximum permitted yield of tar, nicotine or carbon monoxide or more than one of them.

- (2) "Maximum permitted yield" means, in the case of—
- (a) tar, 10 milligrams per cigarette,
 - (b) nicotine, 1 milligram per cigarette, and
 - (c) carbon monoxide, 10 milligrams per cigarette.

Statement of yields on packets of cigarettes

4. - (1) Subject to the following provisions of these Regulations, a producer of cigarettes shall ensure that each packet of cigarettes which he produces provides information as to the tar, nicotine and carbon monoxide yields of the cigarettes contained in it by means of a statement of those yields determined in accordance with ISO4387, ISO8243, ISO8454 and ISO10315.
- (2) The statement—
- (a) as to the tar yield shall be shown as a figure rounded to the nearest whole number and expressed in the form "x mg tar";
 - (b) as to the nicotine yield shall be shown as a figure rounded to one decimal place and expressed in milligrams in the form "x.y mg nicotine";
 - (c) as to the carbon monoxide yield shall be shown as a figure rounded to the nearest whole number and expressed in the form "x mg carbon monoxide".
- (3) The statement of the yields shall—
- (a) be printed on one side of the packet;
 - (b) cover an area amounting to at least 10 per cent of that side of the packet; and
 - (c) comply with the provisions of regulation 9.

Testing of cigarettes, samples and information

- 5.- (1) The Secretary of State may test cigarettes for the purposes of establishing their tar, nicotine and carbon monoxide yields and the accuracy of the statement of those yields on any packet of cigarettes; and in testing the cigarettes the Secretary of State shall select samples in accordance with ISO8243 and conduct the tests in accordance with ISO4387, ISO8454 and ISO10315.
- (2) For the purposes of enabling the Secretary of State to perform his functions under paragraph (1), a producer of cigarettes shall—
- (a) provide the Secretary of State with such samples, at such times and intervals, and from such sources, as the Secretary of State may reasonably require;
 - (b) within the period of one week beginning with the date on which he first supplies a new brand in the United Kingdom notify the Secretary of State of the tar, nicotine and carbon monoxide yields in accordance with ISO4387, ISO8243, ISO8454 and ISO10315 and shown and expressed as specified in regulation 4(2);
 - (c) before 1st October in each year notify the Secretary of State—

- (i) of the names of all brands of cigarettes produced and to be produced by him during the 12 months preceding that 1st October and of the tar, nicotine and carbon monoxide yields determined by the producer in accordance with ISO4387, ISO8243, ISO8454 and ISO10315 and shown and expressed as specified in regulation 4(2), and
 - (ii) of the renaming or discontinuance of any brand produced by him within the 12 months preceding that 1st October.
- (3) In this regulation “new brand” includes a brand of cigarettes which has the same composition as, even if it has a different name from, a brand previously produced, and includes a brand which, though having the same name as one previously produced, has a specification which is sufficiently different to bring about a different yield of tar, nicotine or carbon monoxide.

Procedure for determining yields of tar, nicotine and carbon monoxide

- 6.- (1) Where the Secretary of State considers, having tested cigarettes in accordance with regulation 5(1) that either—
- (a) the yield of tar, nicotine or carbon monoxide exceeds the relevant maximum permitted yield; or
 - (b) the tests do not confirm the accuracy of the yield of tar, nicotine or carbon monoxide notified to him by the producer in accordance with regulation 5(2)(b) or (c),
- he may notify the producer of that opinion and the yields of tar, nicotine and carbon monoxide he considers to be accurate.
- (2) A producer may within one month beginning with the date on which he receives notification under paragraph (1) inform the Secretary of State in writing that he does not agree with the accuracy of the yields notified to him by the Secretary of State, and where he does so he may make representations with a view to agreeing the correct yield with the Secretary of State.
- (3) Where a producer receives notification under paragraph(1)(b) that the Secretary of State’s tests do not confirm the accuracy of the yield of tar, nicotine or carbon monoxide, and he does not inform the Secretary of State in accordance with paragraph (2) that he does not agree with the accuracy of the yields so notified he shall, with effect from the date of expiry of the period of three months beginning with the date on which he receives that notification, provide, as to the information which he is required by regulation 4 to provide on packets of those cigarettes, a statement of the tar, nicotine and carbon monoxide yields as notified by the Secretary of State under paragraph (1).
- (4) Where a producer informs and makes representations to the Secretary of State in accordance with paragraph (2) and—
- (a) they reach agreement within the period of nine months beginning with the date on

which the producer received notification under paragraph (1)—

- (i) the producer shall provide, with effect from three months after the date of the agreement, as the information he is required by regulation 4 to provide, the statement of the tar, nicotine and carbon monoxide yields as so agreed, and
 - (ii) in any proceedings to enforce these Regulations it shall be presumed until the contrary is proved that the tar, nicotine and carbon monoxide yields of cigarettes of the same composition are the yields as so agreed;
- (b) they fail to reach agreement within the period of nine months beginning with the date on which the producer received notification under paragraph (1)—
- (i) the producer shall provide, with effect from three months after the expiry of that period, as the information which he is required by regulation 4 to provide, the statement of tar, nicotine and carbon monoxide yields as notified by the Secretary of State under paragraph (1), or if different, the statement of tar, nicotine and carbon monoxide yields most recently notified to him before the expiry of that period by the Secretary of State, and
 - (ii) in any proceedings to enforce these Regulations it shall be presumed until the contrary is proved that the tar, nicotine and carbon monoxide yields of cigarettes of the same composition are the figures notified to the producer under paragraph (1) or, if different, the figures most recently notified to him before the expiry of that period by the Secretary of State for the purpose of seeking agreement.

Warnings on tobacco products

- 7.- (1) A producer of a tobacco product other than tobacco for oral use and smokeless tobacco products shall ensure that each packet carries—
- (a) on the most visible surface, one of the following warnings—
 - (i) “Smoking kills”,
 - (ii) “Smoking seriously harms you and others around you”; and
 - (b) on the other most visible surface, an additional warning from the list set out in the Schedule.
- (2) A producer of a tobacco product intended only for supply in the travel retail sector may use the warning “Get help to stop smoking: consult your doctor or pharmacist” on that product instead of the warning numbered 10 in the Schedule.
- (3) A producer of a brand of cigarettes shall ensure that—
- (a) each of the warnings in paragraph (1)(a) appears on between 47.5 per cent. and 52.5 per cent; and
 - (b) subject to paragraphs (2) and (4), each of the warnings set out in the Schedule appears on between 4.16 per cent and 8.33 per cent,
- of the total number of packets of cigarettes of that brand which he produces over any period of 12 months.

- (4) In the case of packets other than the packet which immediately encloses the tobacco products, the period for measuring the frequency of the warnings set out in the Schedule as set out in paragraph (3)(b) shall be three years.
- (5) A producer of a smokeless tobacco product shall ensure that its packet carries, on the most visible surface, the warning: “This tobacco product can damage your health and is addictive”.

Size of warnings

- 8.- (1) Subject to paragraph (2), the warnings required in accordance with—
- (a) regulation 7(1)(a) and (4) shall cover an area amounting to at least 30 per cent of the external area of the most visible surface of the packet;
 - (b) regulation 7(1)(b) shall cover an area amounting to at least 40 per cent of the external area of the other most visible surface of the packet.
- (2) Where the area of the most visible surface of the packet of a tobacco product other than cigarettes exceeds 75 cm² the warnings required in accordance with regulation 7(1)(a) and (b) shall each cover an area of at least 22.5 cm².

Appearance of warnings and yield statements

- 9.- (1) On each packet of a tobacco product the text of the yield statements required in accordance with regulation 4 and of the warnings required in accordance with regulation 7 shall be—
- (a) indelible;
 - (b) legible;
 - (c) printed in black Helvetica bold type on a white background;
 - (d) in a font size consistent throughout the text which ensures that the text occupies the greatest possible proportion of the area specified for the relevant statement or warning in regulation 4(3) or 8;
 - (e) in lower-case type, except for the first letter of the text;
 - (f) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;
 - (g) surrounded by a black border outside the area specified for the relevant statement or warning in regulation 4(3) or 8 which shall—
 - (i) be not less than three millimetres and not more than four millimetres in width, and
 - (ii) not interfere with the text of the yield statement or warning;
 - (h) subject to paragraph (2), irremovably printed on the packet.

- (2) In the case of tobacco products other than cigarettes the yield statements and warnings required in accordance with regulations 4 and 7 may be affixed to the packet by means of an irremovable sticker.
- (3) The yield statements and warnings shall not—
 - (a) be printed on the tax stamps on any packet of a tobacco product;
 - (b) be hidden, obscured or interrupted by—
 - (i) other written or pictorial matter, or
 - (ii) the opening of the packet.

Product identification markings

- 10.- (1) A producer of a tobacco product other than tobacco for oral use shall ensure that each packet of that product carries a code marking, whether by batch numbering or otherwise, whereby—
 - (a) the place of its manufacture; and
 - (b) the date and time of its manufacture may be determined.
- (2) A producer of a tobacco product shall provide to the Secretary of State such information as he shall require to enable him to interpret the code marking on that tobacco product for the purpose of any of his functions under these Regulations.

Product descriptions

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

Provision of further product information

- 12.- (1) A producer of tobacco products shall, before 1st October in each year, provide to the Secretary of State for each tobacco product he produces by brand name—
 - (a) a list of all the ingredients of that product which shall—
 - (i) include the quantities of those ingredients, and
 - (ii) be drawn up in descending order of the weight of those ingredients;
 - (b) a statement of the reasons for the inclusion of those ingredients which shall indicate for each ingredient—
 - (i) its function,
 - (ii) its category;
 - (c) all toxicological data available to him concerning the ingredients of that 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 shall 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;
- (d) information concerning the renaming or discontinuation of any brand produced by him within the 12 months preceding that 1st October.

Prohibitions on supply of non-compliant tobacco products

- 13.-(1) No person shall supply any tobacco product in respect of which the producer has not complied with any requirement of regulations 4 to 12 which relates to that product.
- (2) Except in relation to the requirements of regulation 11, paragraph (1) does not apply where a tobacco product is or is to be supplied for consumption outside the United Kingdom.
 - (3) Where in relation to a brand of cigarettes the producer is required by regulation 6 to provide on the packet a statement of tar, nicotine and carbon monoxide yields notified to him by, or agreed with, the Secretary of State, the producer shall not, after the expiry of a period of three months beginning with the date of expiry of the period of nine months mentioned in regulation 6(4)(a) or (b) or the date of the agreement, supply a packet of cigarettes which does not provide that statement.

Enforcement and penalties

- 14.-(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the Consumer Protection Act 1987, these Regulations shall be regarded for the purposes of enforcement (whether by criminal proceedings or otherwise) as safety regulations as defined in that Act^(ff) and except as provided by paragraph (2) any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act^(gg).
- (2) Where a person contravenes the prohibition in regulation 3 on manufacturing cigarettes which exceed the maximum permitted yields that person shall be guilty of an offence and the enforcement provisions of Part IV of the Consumer Protection Act 1987 shall apply to that manufacture as they apply to supply in contravention of a prohibition in safety regulations.
 - (3) Subject to paragraph (4) the requirement of regulation 5(2) to provide samples shall, for the purposes of section 12(4)(a) of the Consumer Protection Act 1987, be treated as though it were a requirement to give information.

^(ff) See sections 11(1) and 45(1) of that Act.

^(gg) See section 45(1) of that Act.

- (4) A person guilty of an offence under paragraphs (2) or (3) shall be liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding level 5 on the standard scale.

Revocations

- 15.-(1) The Cigarettes (Maximum Tar Yield) (Safety) Regulations 1992^(hh) shall be revoked.
- (2) Subject to regulation 16, the following Regulations are revoked—
- (a) The Tobacco Products Labelling (Safety) Regulations 1991⁽ⁱⁱ⁾;
- (b) The Tobacco Products Labelling (Safety) Amendment Regulations 1993^(jj).

Savings and transitional provisions

- 16.-(1) Regulation 5(2)(c) shall have effect in relation to the provision of notification of the carbon monoxide yields of cigarettes as if, for the words, “before 1st October in each year”, there were substituted the words “as soon as reasonably practicable after 30th September 2002, and in any event no later than 31st October 2002”.
- (2) Regulation 12 shall have effect in relation to tobacco products produced during the 12 months preceding 1st October 2002 as if, for the words “before 1st October in each year”, there were substituted the words “as soon as reasonably practicable after 30th September 2002, and in any event no later than 31st December 2002”.
- (3) Regulation 13 shall not apply to the supply of a tobacco product produced before 30th September 2002 where the supply takes or is to take place—
- (a) in the case of cigarettes, before 30th September 2003;
- (b) in the case of other tobacco products, before 30th September 2004,
- provided that, notwithstanding regulation 15(2), such cigarettes and other tobacco products comply until those dates with the relevant provisions of the 1991 Regulations, and for the purposes of this regulation the 1991 Regulations shall continue to apply as though they had not been revoked.
- (4) Notwithstanding regulation 15(2), where on 30th September 2003 the procedure set out in regulation 10 of the 1991 Regulations for determining the statement of tar and nicotine yields on cigarette packets has been commenced in relation to a brand of cigarettes by notification by the Secretary of State to its producer, regulation 10 of the 1991 Regulations shall continue to apply to the determination of the tar and nicotine yields of that brand of cigarettes until the statements of tar and nicotine

^(hh) S.I. 1992/2783.
⁽ⁱⁱ⁾ S.I. 1991/1530.
^(jj) S.I. 1993/1947.

yields are provided in accordance with regulation 10(3) of the 1991 Regulations as though the 1991 Regulations had not been revoked.

Signed by authority by the Secretary of State for Health

Date

Parliamentary Under Secretary of State
Department of Health

SCHEDULE Regulation 7

List of additional health warnings

1. Smokers die younger.
2. Smoking clogs the arteries and causes heart attacks and strokes.
3. Smoking causes fatal lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: don't make them breath your smoke.
6. Your doctor or your pharmacist can help you stop smoking.
7. Smoking is highly addictive, don't start.
8. Stopping smoking reduces the risk of fatal heart and lung diseases.
9. Smoking can cause a slow and painful death.
10. Get help to stop smoking: ring 0800 169 0 169.
11. Smoking may reduce the blood flow and causes impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage the sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

Appendix 3

Text of Directive 2001/37/EC

Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

Official Journal L 194 , 18/07/2001 P. 0026 - 0035

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee⁽²⁾,

Having regard to the opinion of the Committee of the Regions⁽³⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽⁴⁾, in the light of the joint text approved by the Conciliation Committee on 5 April 2001,

Whereas:

(1) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use⁽⁵⁾ was amended substantially by Directive 92/41/EEC⁽⁶⁾. Since further amendments are to be made to that Directive, as well as to Council Directive 90/239/EEC of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes⁽⁷⁾, those Directives should be recast in the interests of clarity.

(2) There are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation, and sale of tobacco products which impede the functioning of the internal market.

(3) Those barriers should be eliminated and, to this end, the rules relating to the manufacture, presentation and sale of tobacco products should be approximated, while leaving Member States the possibility of introducing, under certain conditions, such requirements as they consider necessary in order to guarantee the protection of the health of individuals.

(4) In accordance with Article 95(3) of the Treaty, a high level of protection in terms of health, safety, environmental protection and consumer protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts; in view of the particularly harmful effects of tobacco, health protection should be given priority in this context.

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

(6) Directive 89/622/EEC established a general warning to be carried on the unit packaging of all tobacco products, together with additional warnings exclusively for cigarettes and, from 1992, extended the requirement for additional warnings to other tobacco products.

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

(8) A revision of the regulatory framework needs to evaluate evidence-based claims for tobacco products designed and/or marketed to "reduce risk", or for which harm reduction is claimed by the manufacturers.

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

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

(11) This Directive will also have consequences for tobacco products which are exported from the European Community. The export regime is part of the common commercial policy. Health requirements are, pursuant to Article 152(1) of the Treaty and the case law of the Court of Justice of the European Communities, to form a constituent part of the Community's other policies. Rules should be adopted in order to ensure that the internal market provisions are not undermined.

(12) The provisions of this Directive are without prejudice to Community legislation governing the use and labelling of genetically modified organisms.

(13) Internationally applicable standards for tobacco products are one of the subjects of the negotiations for the drafting of a World Health Organisation Framework Convention on Tobacco Control.

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

(15) There are no internationally agreed standards or tests for quantifying and assessing the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide. A procedure for development of such standards, in consultation with the International Standards Organisation, is therefore necessary.

(16) In Directive 90/239/EEC, in view of particular socioeconomic problems, Greece was granted a derogation from the time limits for the implementation of maximum tar yields. That derogation should be maintained for the period stipulated.

(17) The application of tar, nicotine and carbon monoxide ceilings to exported cigarettes should be subject to transitional arrangements in order to allow more time to change product specifications and to allow for the establishment of internationally agreed standards.

(18) Transitional periods should also be provided for in relation to other provisions of this Directive in order to allow the necessary modifications in production to take place and for disposal of stocks, particularly for products other than cigarettes. Use of irremovable labels should be allowed to facilitate the introduction of the labelling requirements of this Directive.

(19) The presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. It is necessary to that end that the existing legislation be strengthened and clarified, while ensuring a high level of health protection.

(20) Provision should be made for batches of tobacco products to be marked so that those products are traceable for the purposes of monitoring compliance with this Directive.

(21) The direct and indirect socioeconomic costs of active and passive tobacco use should be regularly evaluated and made available to the public in the context of the appropriate Community programmes.

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

(23) The lack of information together with the lack of toxicological data prevents the relevant authorities in the Member States from assessing in any meaningful manner the toxicity of, and hazards posed to the health of the consumer by, tobacco products. This is inconsistent with the obligation placed on the Community to ensure a high level of protection for human health.

(24) Member States should be able to adopt more stringent rules concerning tobacco products which they deem necessary to protect public health, in so far as the rules in the Directive are not prejudiced, and subject to the provisions of the Treaty.

(25) Pending the establishment of the common list of ingredients referred to in Article 12, Member States may provide for the prohibition of the use of ingredients which have the effect of increasing the addictive properties of tobacco products, since the use of such ingredients may undermine the limits on nicotine levels laid down in this Directive.

(26) Tobacco products have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt. In recent years it has also been shown that passive smoking is dangerous in particular to unborn children and infants and that it can cause or aggravate respiratory problems in persons inhaling smoke. Moreover, 80 % of new smokers in the Community are below the age of 18. The greatest possible transparency of product information should be ensured, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the tobacco manufacturers.

(27) 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. Smoking behaviour and addiction, and not only the content of certain substances contained in the product before consumption, also determine the level of inhaled substances. This fact is not reflected in the use of such terms and so may undermine the labelling requirements set in this Directive. In order to ensure the proper functioning of the internal market, and given the development of proposed international rules, the prohibition of such use should be provided for at Community level, giving sufficient time for introduction of this rule.

(28) Directive 89/622/EEC prohibited the sale in the Member States of certain types of tobacco for oral use. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden a derogation from the provisions of that Directive in this regard.

(29) Technical and scientific progress in the field of tobacco products calls for regular re-evaluation of the provisions and the application of this Directive in Member States. To that end provision should be made for a procedure for the Commission to draw up regular reports supported by scientific and technical data. Certain data ought to be examined with particular attention in this context.

(30) In connection with the fixing of maximum yields, it ought to be considered whether, on the one hand, it is advisable at a later date to reduce the yields fixed and in particular how, if at all, they are connected and, on the other hand, whether standards on these matters should be developed for products other than cigarettes, in particular rolling tobacco.

(31) As regards tobacco products other than cigarettes, standards and measurement methodologies need to be developed at Community level, and to this end the Commission should be requested to submit appropriate proposals.

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

(33) The size of the internal market in tobacco products and the increasing tendency of tobacco manufacturers to concentrate production for the whole of the Community in only a small number of production plants within the Member States, calls for legislative action to achieve the smooth operation of the internal market in tobacco products to be carried out at Community rather than national level.

(34) The functioning of the common organisation of the market in raw tobacco is to be the subject of a Commission report to the European Parliament and Council in 2002⁽⁸⁾. The Commission has indicated that such report will also examine the issue of integration of public health considerations, including the standards established in this Directive, in other Community policies, as required under Article 152 of the Treaty.

(35) In applying this Directive, provision should be made for establishing time limits which allow, on the one hand, completion to a maximum degree of efficiency of the process of conversion already begun by Directive 90/239/EEC, and, on the other, consumers and manufacturers to adapt to products with a lower tar, nicotine and carbon monoxide yield.

(36) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁹⁾.

(37) This Directive should be without prejudice to the time limits within which the Member States must transpose and apply the Directives set out in Annex II,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Aim

The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products, taking as a basis a high level of health protection.

Article 2

Definitions

For the purposes of this Directive:

1. "tobacco products" means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not;

2. "tar" means the raw anhydrous nicotine-free condensate of smoke;
3. "nicotine" means nicotinic alkaloids;
4. "tobacco for oral use" means 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;
5. "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.

Article 3

Cigarettes: maximum tar, nicotine and carbon monoxide yields

1. From 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than:
 - 10 mg per cigarette for tar,
 - 1 mg per cigarette for nicotine,
 - 10 mg per cigarette for carbon monoxide.
2. By way of derogation from the date referred to in paragraph 1, as regards cigarettes manufactured within, but exported from, the European Community, Member States may apply the yield limits laid down in this Article as from 1 January 2005 but shall in any event do so by 1 January 2007 at the latest.
3. For Greece, as a temporary derogation, the date of application of the maximum tar yield of cigarettes manufactured and marketed within its territory, as referred to in paragraph 1, shall be 1 January 2007.

Article 4

Measurement methods

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

The accuracy of the tar and nicotine indications on packets shall be verified in accordance with ISO standard 8243.

2. The tests referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, by 30 September 2002, and whenever any change is made.

3. Member States may also require tobacco manufacturers or importers to carry out any other tests as may be laid down by the competent national authorities 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. Member States may also require that such tests be carried out or verified in approved testing laboratories as laid down in paragraph 2.

4. The results of tests carried out in accordance with paragraph 3 shall be submitted to the relevant national authorities on an annual basis. Member States may provide for less frequent disclosure of test results in cases where the product specifications have not varied. Member States shall be informed of changes in such product specifications

Member States shall ensure the dissemination, by any appropriate means, of information submitted in accordance with this Article with a view to informing consumers and in so doing shall take account, where appropriate, of any information which constitutes a trade secret.

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

Article 5 Labelling

1. The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Article 4 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.

That percentage shall be raised to 12 % for Member States with two official languages and to 15 % for Member States with three official languages.

2. Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products must carry the following warnings:

(a) general warnings:

1. "Smoking kills/Smoking can kill," or
2. "Smoking seriously harms you and others around you."

The general warnings indicated above shall be rotated in such a way as to guarantee their regular appearance. The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product; and

(b) an additional warning taken from the list set out in Annex I.

The additional warnings referred to above shall be rotated in such a way as to guarantee their regular appearance.

That warning shall be printed on the other most visible surface of the unit packet, and on any

outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warnings on those surfaces in order to accommodate language requirements.

3. The Commission shall, as soon as practicable and in any event not later than 31 December 2002, in accordance with the procedure laid down in Article 10(2), adopt rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking, with a view to ensuring that internal market provisions are not undermined.

Where Member States require additional warnings in the form of colour photographs or other illustrations, these shall be in accordance with the abovementioned rules.

4. Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products shall carry the following warning:

"This tobacco product can damage your health and is addictive."

This warning shall be printed on the most visible surface of the unit packet and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warning on that surface in order to accommodate language requirements.

5. The general warning required pursuant to paragraph 2(a) and the warning for smokeless and oral tobacco products referred to in paragraph 4 shall cover not less than 30 % of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40 % of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with three official languages.

However, in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm², the warnings referred to in paragraph 2 shall cover an area of at least 22,5 cm² on each surface. That area shall be increased to 24 cm² for Member States with two official languages and 26,25 cm² for Member States with three official languages.

6. The text of warnings and yield indications required under this Article shall be:

(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States shall have the right to determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;

(b) in lower-case type, except for the first letter of the message and where required by grammar usage;

(c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;

(d) for products other than those referred to in paragraph 4, 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;

(e) in the official language or languages of the Member State where the product is placed on the market.

7. The printing of the texts required by this Article on the tax stamps of unit packets shall be prohibited. The texts shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

8. Member States may stipulate that the warnings referred to in paragraphs 2 and 4 are to be accompanied by a reference, outside the box for warnings, to the issuing authority.

9. To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

The technical measures to apply this provision shall be adopted in accordance with the procedure laid down in Article 10(2).

Article 6

Further product information

1. Member States shall require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.

This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product.

The information referred to in the first subparagraph shall be provided on a yearly basis and for the first time by 31 December 2002 at the latest.

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

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

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

Article 7 **Product descriptions**

With effect from 30 September 2003, and without prejudice to Article 5(1), 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.

Article 8 **Tobacco for oral use**

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Article 9 **Adaptations**

The Commission shall, in accordance with the procedure laid down in Article 10(2), adapt to scientific and technical progress:

- (a) the measurement methods laid down in Article 4 and the definitions relating thereto;
- (b) the health warnings to be shown on unit packets of tobacco products as set out in Annex I and the frequency of rotation of the health warnings;
- (c) the marking for identification and tracing purposes of tobacco products.

Article 10 **Regulatory procedure**

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 11 **Report**

No later than 31 December 2004, and every two years thereafter, the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on the application of this Directive.

With a view to drafting the report referred to in the first paragraph, 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 maximum yields laid down in Article 3(1),
- 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.

The report shall also examine the links between the labelling requirements laid down in Article 5 and consumer behaviour. That report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco products, to the extent necessary for the establishment and operation of the internal market, and to take into account any new development based on scientific facts and developments on internationally agreed product standards.

Article 12

Common list of ingredients

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

Article 13

Import, sale and consumption of tobacco products

1. Member States may not, for considerations relating to the limitation of the tar, nicotine or carbon monoxide yields of cigarettes, to health warnings and other indications or to other requirements of this Directive, prohibit or restrict the import, sale or consumption of tobacco

products which comply with this Directive, with the exception of measures taken for the purposes of verifying the data provided under Article 4.

2. This Directive shall not affect the right of Member States to keep or introduce, in accordance with the Treaty, more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order to protect public health, in-so-far as such rules do not prejudice the rules laid down in this Directive.

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

Article 14 **Implementation**

1. Without prejudice to the first paragraph of Article 15, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 2002 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Products which do not comply with the provisions of this Directive may continue to be marketed for one year after the date referred to in paragraph 1.

3. By way of derogation from paragraph 2, products other than cigarettes which do not comply with the provisions of this Directive may continue to be marketed for two years after the date referred to in paragraph 1.

4. Member States shall communicate to the Commission the text of the provisions of domestic law which they adopt in the field governed by this Directive.

Article 15 **Repeal**

Directives 89/622/EEC and 90/239/EEC are hereby repealed, without prejudice to the obligations of Member States concerning the time limits for transposition and application of the Directives listed in Annex II.

References to the Directives repealed shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 16 **Entry into force**

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 5 June 2001.

For the European Parliament
The President
N. Fontaine

For the Council
The President
L. Engqvist

⁽¹⁾ OJ C 150 E, 30.5.2000, p. 43 and OJ C 337 E, 28.11.2000, p. 177.

⁽²⁾ OJ C 140, 18.5.2000, p. 24.

⁽³⁾ OJ C 226, 8.8.2000, p. 5.

⁽⁴⁾ Opinion of the European Parliament of 14 June 2000 (OJ C 67, 1.3.2001, p. 150), Council Common Position of 31 July 2000 (OJ C 300, 20.10.2000, p. 49.) and Decision of the European Parliament of 13 December 2000 (not yet published in the Official Journal). Decision of the European Parliament of 15 May 2001 and Decision of the Council of 14 May 2001.

⁽⁵⁾ OJ L 359, 8.12.1989, p. 1.

⁽⁶⁾ OJ L 158, 11.6.1992, p. 30.

⁽⁷⁾ OJ L 137, 30.5.1990, p. 36.

⁽⁸⁾ Article 26 of Council Regulation (EEC) No 2075/92 of 30 June 1992 on the common organisation of the market in raw tobacco (OJ L 215, 30.7.1992, p. 70), as amended by Regulation (EC) 1636/98 of 20 July 1998 (OJ L 210, 28.7.1998, p. 23).

⁽⁹⁾ OJ L 184, 17.7.1999, p. 23.

ANNEX I

List of additional health warnings (referred to in Article 5(2)(b))

1. Smokers die younger.
2. Smoking clogs the arteries and causes heart attacks and strokes.
3. Smoking causes fatal lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: don't make them breathe your smoke.
6. Your doctor or your pharmacist can help you stop smoking.
7. Smoking is highly addictive, don't start.
8. Stopping smoking reduces the risk of fatal heart and lung diseases.
9. Smoking can cause a slow and painful death.
10. Get help to stop smoking: (telephone/postal address/internet address/consult your doctor/pharmacist).
11. Smoking may reduce the blood flow and causes impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage the sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

ANNEX II

Time-limits for transposition and implementation of repealed Directives (referred to in Article 15)

Directive	Time limits for transposition	Time limits for application
89/622/33C (OJ L 359, 8.12.1989, p.1)	1 July 1990	31 December 1991 31 December 1992 31 December 1993
90/239/EEC (OJ L 137, 30.5.1990, p. 36)	18 November 1991	31 December 1992 ⁽¹⁾ 31 December 1997 ⁽¹⁾ 31 December 1992 ⁽²⁾ 31 December 1998 ⁽²⁾ 31 December 2000 ⁽²⁾ 31 December 2006 ⁽²⁾
92/41/EEC (OJ L 158, 11.6.1992, p. 30)	1 July 1992	1 July 1992 1 January 1994 31 December 1994
⁽¹⁾ For all Member States except Greece ⁽²⁾ Derogation applying to Greece only		

