



European Community Directive on packaging and labelling of tobacco products

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Directive 2001/37/EC of 5 June 2001 concerning the manufacture, presentation and sale of tobacco products was published in the Official Journal of the European Communities on 18 July 2001. It was introduced in the national legislation of the 15 European Union (EU) Member States on 30 September 2002. The Directive contains provisions on maximum yields, warning labels, reporting requirements, misleading descriptors, traceability, monitoring and review. This paper discusses the provisions on packaging and labelling and assesses their impact.

History of the packaging and labelling of tobacco products in the European Union

The Treaty of Rome, which established the Community in 1957, did not contain a specific article that gave the community competence in public health. In 1985, two political leaders—President Mitterrand of France and Prime Minister Craxi of Italy—felt strongly that the Community should become more involved in public health. At their bi-annual meeting in Milan in 1985, the heads of state and of Governments of the Member States of the European Community called on the Commission to launch a European Programme against Cancer⁽¹⁾. A high-level cancer-expert committee was established to advise the European Commission. At its meeting in February 1986 a comprehensive set of measures to combat cancer was formulated. An action plan was elaborated upon with the aim of reducing the number of deaths by 15% in 2000. Fourteen of the proposed actions of the “Europe against Cancer” programme were related to tobacco control. One of proposed measures was to introduce European tobacco labelling legislation.

The European Community legislative process is long and complex and cannot be described in detail in this paper. The lobbying activities around these directives were described by Michel Richonnier, who was in charge of the Programme “Europe against Cancer” during the period 1996–2001 (2). The tobacco industry was strongly opposed to new legislative measures and was omnipresent at every level of European decision-making. The tobacco industry put heavy pressure on governments to oppose the directive.

At the Council of Ministers on 16 May 1989, the British Minister of Health voted against the directive since the Government of the United Kingdom felt that the Community had no health competence to introduce such

legislation. The German Government was another target in the tobacco industry's strategy. Ridiculing the health consequences was one of their tactics. Another was to advance the argument that the proposed Directive would be violating the German constitution. The tobacco industry's strategy failed in the short term since the German Government supported the first Labelling Directive (89/622) in 1989(2). In the long term, however, the tobacco industry strategy was successful because the German Government would eventually become the industry's strongest ally in Europe.

The European labelling legislation finally resulted in two legislative measures: Directive 89/622 of 13 November 1989 and Directive 92/41 of 15 May 1992. This legislation pushed Member States, many of whom had had little or no legislation on labelling, to adopt a system of warnings and product information that is relatively satisfactory from a public health point of view, in particular, the introduction of rotating warnings. However, despite the amendments adopted in 1992, which reinforced, in particular, the labelling of tobacco products other than cigarettes, the European legislation had several weaknesses that needed to be addressed. The two weak points of the Directives' labelling requirements were the warnings' small size and lack of visibility.

The small size of the warnings

According to the Directive 89/622, the general warning and the specific warnings must cover at least 4% of each of the large surfaces of the cigarette pack, excluding the indication of the authority that is author of the warnings. Warnings should ideally be printed in sufficiently large characters so as to be easily read by the consumer. This means that a large area of the pack needs to be reserved for this purpose. In this context, the 4% of the pack planned in the Directive seemed derisory. This was confirmed by research inside and outside the EU. The following two findings demonstrate this point:

- Qualitative research and quantitative research among 2 000 adults in the United Kingdom in November 1990 to test the new EU health warnings concluded that:

the impact of the new pack warnings is likely to be marginal whatever the nature of the message, because of their comparatively small size. At 4% of the pack face, they are difficult for many to read, and comparatively easy to ignore. There is a tendency to interpret the smallness of the warnings as evidence of government complicity. More worryingly,



there seems to be a tendency to equate the size of the warning with the magnitude of the risk ⁽³⁾.

- Despite the fact that EU legislation on labelling came into force on 1 January 1992 and contained an obligation to have warnings on the front and the back of the packs, research in 1997 among 1 000 people in the United Kingdom showed that:
only 29% of the smokers, 28% of the ex-smokers and 30% of the non-smokers were able to say that the warning was printed on the front of the pack ⁽⁴⁾.

The lack of visibility

Another vulnerable point of the Directive was the requirement that warnings be printed on a contrasting background. In the Oxford English dictionary “contrasting” is defined as “a juxtaposition or comparison showing striking differences”. According to a report undertaken by the European Bureau for Action on Smoking Prevention (BASP) at the request of the Commission of the European Communities, the contrasting background was a major problem. In August 1993, a survey of the top five cigarette brands in the EU countries, which covered some 60% of the European cigarette market, indicated that the colour gold was used for the lettering of the warnings on 68% of the packs. The use of gold lettering was considered by the authors to be against the spirit of the EU Directive because as a reflective colour it offered only a minimal contrast. A number of other colour combinations were also felt to have been chosen deliberately with a view to minimizing the warning’s visibility (grey on white, blue on darker blue, etc.) In certain cases, the choice of colour was felt to so severely undermine the intention of EU legislation as to be contravening the Directive ⁽⁵⁾.

The new labelling provisions of the Directive 2001/37/EC

The main criticism of the previous legislation on labelling was the warning’s lack of visibility as a result of its small size and the colour of the lettering, which failed to adequately contrast with the background colour of the pack. New EU legislation (Directive 2001/37/EC) would increase the size of warnings (from 4% to 30% and 40%) and stipulate in very precise terms in which colours the warnings should be printed (black on white, surrounded by a black border).

The main provisions on packaging and labelling in the Directive 2001/37/EC are the following:

- The tar, nicotine and carbon monoxide yields of cigarettes shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered (12% for two official languages and to 15% for three official languages).
- Warning labels should cover 30% of the front of the pack (32% for two languages and 35% for three languages) and 40% of the back of the pack (45% for two languages and 50% for three languages).
- Warning texts should contain a general warning on the front—either “Smoking kills” (or “can kill”, depending upon transposition) or “Smoking seriously harms you and those around you” to be rotated on a regular basis; additional warnings on the back—a list of about 12 different texts, also to be alternated on a regular basis.
- The text of warnings and yield indications shall be printed in black Helvetica bold type on a white background; in lower case type, except for the first letter of the message and where required by grammar usage; centred in the area in which the text is required to be printed, parallel to the top edge of the packet; surrounded by a black border not less than 3 mm and not more than 4 mm in width, which in no way interferes with the text of the warning or information given; in the official language or languages of the Member State where the product is placed on the market.

The Commission prepared rules for the use of colour photos (e.g. as recently introduced in Canada), graphics, etc. on 5 September 2003. Member States that wish to authorize the use of pictures, etc. would then still be entitled to do so, but only within the context of the agreed rules. The implementation of the use of colour photographs or other illustrations as health warnings shall apply as of 1 October 2004 at the earliest (Commission Decision of 5 September 2003).

- Mechanisms were introduced to ensure that the implementation of the Directive is properly monitored and that the provisions of the Directive are kept up-to-date in terms of scientific developments. The Commission shall be assisted by a committee of representatives of the Member States to adapt to scientific and technical progress: the maximum yield measurement methods and the definitions relating thereto; the health warnings and the frequency of rotation of



the health warning and the marking for identification and tracing purposes of tobacco products.

- No later than 31 December 2004, the Commission shall submit a report on the application of this Directive and shall pay special attention, among other things, to:
 - 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,
 - development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide.

Implementation of the Directive 2001/37/EC

Directive 2001/37/EC of 5 June 2001 concerning the manufacture, presentation and sale of tobacco products had to be introduced in the national legislation of the 15 EU Member States by 30 September 2002. Products that did not comply with the warning provisions of the Directive could continue to be marketed until 30 September 2003. The ten European accession countries, which will join the European Union in May 2004, also have to introduce the Directive into their legislation according to a time table agreed upon with the EU.

The impact of labeling regulation cannot yet be measured since the new warnings have not been available in most EU countries until recently. Cigarette packs with the new, bigger health warnings have only been on sale in the Netherlands since 1 May 2002 (Decree of 21 January 2002).

The Directive was challenged in the European Court of Justice by British American Tobacco, Imperial Tobacco and Japan Tobacco International. The Advocate General of the European Court of Justice published its Opinion on 10 September 2002 on the legal challenges to the Tobacco Products Directive. He believes that the Directive is valid, and recommends that the Court should rule accordingly. On 10 December 2002, the Court decided to uphold the validity of the Directive. (Case 491/01). This decision can be considered as a major setback for the tobacco industry.

There has been discussion as to whether the three-millimetre black border surrounding the warnings should

be additional to the health warning area or part of it. In Sweden, the National Institute of Public Health decided that the black border should be additional to the warning, which resulted in a legal challenge by Philip Morris on the interpretation of this article of the Directive in Sweden. The tobacco industry lost this case. On 10 October 2002, the Swedish Cabinet of Government Ministers decided on the case and rejected the arguments of Philip Morris. The black border interpretation has not led to legal challenges in other countries. In Belgium, for instance, provisions regarding the black border are laid down in Article 3 of the Royal Decree of 29 May 2002. In the comments to this new Article, it is clearly laid down that the texts in question shall be surrounded—in addition—by a black border. It is also being stated that the EU Commission officially has confirmed that the Directive thereby has been correctly implemented in Belgian legislation. Moreover, the Belgian constitutional court (Conseil d'Etat, legal advice of 19 February 2002) agreed with this interpretation, acknowledging that only the European Court Justice will have a final say on this interpretation. Considering that Belgium has three official languages, which increases the size of warnings from 30% to 35% and from 40% to 50%, adding the black border in addition to the warnings, means that in that country the size of the warnings will be 46% of the front and 62% of the back of the cigarette packs.

The new EU warnings have been warmly welcomed by health organizations. The only major criticism of the new legislation is the printing of the tar, nicotine and carbon monoxide yields of cigarettes on the packs, since the tar and nicotine yields are based on ISO measurements and do not provide meaningful information for consumers. One of the recommendations of the WHO conference *Advancing knowledge on regulating tobacco products*, was to remove these yields from the packs ⁽⁶⁾. During the discussions on the directive, some representatives of health ministries felt that it would be wrong not to provide the consumers with any information on the yields on the packs.

Impact of the labeling provisions

In most EU countries the new health warnings have not been visible until recently on cigarette packs. Products that do not comply with the warning provisions of the Directive could continue to be marketed until 30 September 2003. The exception is the Netherlands, where tobacco products with the new warnings have been on the market since May 2002. On 26 November 2002, the Dutch organiza-



tion *Defacto* presented the results of two Dutch studies on the effects of the new health warnings on the cigarette packages. One study was conducted among a representative sample of 7 387 adults, the other among 299 youngsters. Nine per cent of the adult smokers, who had seen the new warnings said they smoked less and 16% were more motivated to quit. The effect of the warnings was even stronger on adolescents (13–18-year-olds) Twenty-eight per cent of youngsters said they smoked less because of the new health warnings. Moreover, the results showed that very few youngsters thought the new warnings were “cool”. Only 5% of the youngsters, who knew about the new health warnings, tried to collect all 14 warnings ⁽⁷⁾.

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