

Bundesrat

Decision of the Bundesrat

Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

COM(2012) 788 final; Council document 18068/12

The Bundesrat, in its 908th session on 22 March 2013, under Sections 3 and 5 of the Act on Cooperation between the Federation and the *Länder* in European Union Affairs (EUZBLG), adopted the following opinion:

On the Proposal in general

1. The Bundesrat broadly welcomes the EU Proposal on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and the extension of these provisions to related products. It expressly supports the goals of better child protection, health protection and non-smoker protection, which should be prioritised over other aspects.
2. Given that large numbers of people are still falling ill and dying as a result of tobacco consumption, it is sensible and necessary to take further measures to curb it. Those provided for in the Proposal, e.g. increasing the size of warnings on tobacco packaging, in combination with additional pictorial warnings, are suitable ways of doing this.
3. The Bundesrat notes that implementing the Proposal for a Directive could lead to a loss of sales for the tobacco industry and its suppliers. These losses are justifiable

to the extent that they lead to a higher level of child protection, health protection and non-smoker protection in Europe.

4. The Bundesrat therefore calls on the Federal Government to examine the extent to which the interests of the companies affected can be taken into account without placing in jeopardy the objectives pursued by the Proposal for a Directive. The focus should be on small and medium-sized enterprises.
5. In particular, provisions relating only to small segments of the market and which therefore, under certain circumstances, provide only limited health and child protection benefits should be examined. Such provisions risk hindering product innovation and, for example in the tobacco production machine building industry, will lead to a devaluation of investment and threaten business models.
6. The idea of generic packaging for all tobacco products ("standard packaging") is rejected by the Bundesrat for economic and health reasons. The Commission has rightly distanced itself from this approach. It should be ensured that the planned combined warnings on packaging (75 percent of the front and back and 50 percent of the sides) give manufacturers enough scope for brand and product differentiation. Otherwise, we may see an increase in counterfeit products and thus an undermining of the health objectives of the Proposal for a Directive.
7. The Bundesrat is sceptical about some of the delegated acts and implementing acts provided for in the Proposal. It therefore calls on the Federal Government in the further negotiations to ensure that the legal acts in question are examined not only in terms of competences but, in particular, in terms of their potential impact on firms affected along the value creation chain.
8. The Bundesrat would like to see the following improvements made to the following articles:

Article 2 "Definitions"

9. The definitions should be listed alphabetically so that they are easy to consult.
10. According to the definitions, 'maximum level' or 'maximum yield' means the maximum content or emission of a substance in a tobacco product measured in grams. The extent to which measuring uncertainty is to be taken into account in the evaluation of the manufacturer's maximum values and in official supervision should be defined.
11. The term 'water pipe tobacco' should be included in the definitions. There is no direct combustion in the smoking of water pipe tobacco, so its inclusion as 'pipe tobacco', in accordance with the definition in Article 2(26) is not possible.
12. The following definition of 'characterising flavour' is proposed:
A 'characterising flavour' is a flavour distinguishable or different from tobacco which is achieved through the use of an additive or a combination of additives and which can be perceived before or during the intended use of the tobacco product.
13. Furthermore, a definition of "Non tobacco products", as in the heading of Title III, should be included.

Article 3 "Maximum tar, nicotine, carbon monoxide and other yields "

14. The term "threshold of addictiveness" used in Article 3(3) should be defined in Article 2.
15. The reintroduction of the "threshold of toxicity" is welcomed, but it should be defined in more detail in Article 2. It is also proposed that particularly dangerous emissions in cigarettes should be given toxicity indices so that a 'toxicity threshold' can be established accurately and then used for all new products as the upper limit for placing on the market.

Article 4 "Measurement methods"

16. According to the second subparagraph of Article 4(1), the accuracy of the tar and nicotine indications should be verified in accordance with ISO standard 8243. There is no mention of the fact that the accuracy of the carbon monoxide indications should also be verified in accordance with ISO standard 8243.
17. The sensory perception of flavours differs widely between individuals and is very

subjective. Clear evaluation and measuring methods should be established for the supervisory authorities to determine whether these are "characterising flavours". However, there are currently no binding evaluation or measuring methods. Menthol in particular, but also confectionary, fruit, chocolate/cocoa and vanilla-like flavourings should all be banned in the manufacture of tobacco products. The supervisory authorities can use analytical methods to test for the presence of certain flavourings and objectively test suitability for placing on the market.

Corresponding measuring methods to test for certain flavourings should be established.

Article 5 "Reporting of ingredients and emissions"

18. The planned obligation on manufacturers of tobacco products to send to the competent authorities a list of all ingredients and quantities in their products, as well as the emissions, is not precise enough. The term "emissions" should be defined in more detail, e.g. with regard to substances with a health impact.

Manufacturers and importers can, in the measurement of emissions (except tar, nicotine and carbon monoxide), choose their own measuring procedures, and the use of different measuring procedures means that the data reported are not comparable. It is proposed that standardised measuring procedures be developed and made binding. Moreover, the information falling under trade secrecy should be defined in more detail.

Article 6(1), (5) and (10) "Regulation of ingredients"

19. Article 6(1), (5) and (10) of the Proposal for a Directive provide that characterising flavours for cigarettes, roll-your-own tobacco and smokeless tobacco products should be prohibited. The Bundesrat proposes that the exemptions be defined more broadly because, like cigarette formats, a ban on flavourings and additives will not, in itself, lead to a higher level of health protection for the population. According to the Proposal for a Directive, exemptions are available for other tobacco products such as cigars, cigarillos and pipe tobacco.

20. The Federal Government is therefore requested to push, in the further negotiations at EU level, for snuff and chewing tobacco to also be exempted from the bans in Article 6(1) and (5), in addition to cigars, cigarillos and pipe tobacco.

Article 6(1) of the Proposal for a Directive provides that the Member States should prohibit the placing on the market of tobacco products whose flavour has been excessively modified by flavourings such as menthol, fruit or chocolate. The ban on 'characterising flavours' applies to cigarettes, roll-your-own and smokeless tobacco products but not to tobacco products such as cigarillos, cigars or pipe

tobacco. As snuff is a smokeless tobacco and, as a rule, contains menthol as a characterising flavour, the new provisions will lead to a ban on traditional snuff. As chewing tobacco is also a smokeless form of tobacco to which flavouring is added during the manufacturing process, it will also be affected by the new prohibitions.

The Commission justifies the ban on flavour modification on the grounds of child protection and protection against addiction. Covering up the tobacco flavours can induce young people in particular to smoke. However, tobacco products such as cigars, cigarillos and pipe tobacco should be exempted from the ban on characterising flavours as they are, as a rule, consumed by older people. The same applies to snuff and chewing tobacco, also generally consumed by older people. The goal of child protection and addiction prevention will not be achieved by targeting snuff and chewing tobacco, so treating snuff and chewing tobacco more severely compared to other products such as cigars, cigarillos and pipe tobacco is not justified.

The special position of cigars, cigarillos, pipe tobacco, snuff and chewing tobacco can also be seen in the fact that the labelling obligations under Articles 10 and 11 of the Proposal for a Directive are less restrictive than the labelling provisions for cigarettes and roll-your-own tobacco (see Article 10(1), sentence 1, and Article 11 of the Proposal for a Directive).

Article 6(4) "Regulation of ingredients"

21. The ban on the use of additives should be supplemented by: "d) additives which increase the addictiveness of nicotine".

Article 12 "Product description"

22. This article should be complemented with a provision on organic tobacco. So far, packaging for this product has mentioned that it is organic but warned that the smoke from organic tobacco products is no less dangerous than smoke from other tobacco products. This explicit indication of the fact the product is as dangerous to health as traditional tobacco prevents consumers being misled by the labelling.

Article 13(1) "Appearance and content of unit packets"

23. The Federal Government is called on to push, in the further negotiations at EU level, for the restriction on the type of packaging for roll-your-own tobacco, i.e. imposing the form of a pouch, to be withdrawn so as to allow manufacturers to continue to use other packaging solutions for this product group.

Article 13(1) of the Proposal for a Directive contains the provision that a unit packet of roll-your-own tobacco should have the form of a pouch. In general, the

stricter provisions of the Proposal for a Directive, e.g. the larger warning notices for cigarettes and for roll-your-own tobacco, are welcome from a health policy perspective. However, the planned prohibition of, for example, composite tins by limiting the permissible packaging types to pouches will not lead to a significant improvement in public health protection, particularly as consumers can be protected by warnings on the packaging in line with the "Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control".

Article 15 "Tobacco for oral use"

24. In addition to the usual tobacco products for oral use, products have now come onto the market which are similar in terms of their make-up but do not contain nicotine or tobacco and which are used orally, like tobacco products. The use of such products can tempt consumers to try oral tobacco products.

These products do not currently fall within the scope of the Proposal for the new Directive, as they are neither tobacco products nor are they covered by the provisions of Title III of the Proposal for a Directive.

However, they should be included in the Proposal.

Article 18 "Nicotine-containing products"

25. In line with Article 6 of the Proposal for a Directive ("Regulation of ingredients"), which applies to tobacco products, the placing on the market of "nicotine-containing products" with characterising flavours, colourings, caffeine, taurine and vitamins should be prohibited if at all possible, or at least regulated. Flavourings and colourings significantly increase the acceptance of these products among consumers, and the danger exists that more people who are unaware of the content and effect of these products will develop a nicotine addiction. The probability of children poisoning themselves by inadvertently ingesting such products is much less if the products are not flavoured or coloured.

26. Labelling of "nicotine-containing products"

Nicotine contents should be marked on the product (as a clear statement of the concentration, e.g. mg per ml). In addition to the warning pursuant to Article 18(3) of the Proposal, it would be sensible to also include a warning that the product should be kept out of the reach of children. The solutions used in electronic cigarettes in particular can be very toxic for children – depending on the nicotine content, the absorption of just a few millilitres of solution can result in poisoning or even death for children.

27. Packaging of "nicotine-containing products"

Because nicotine-containing products are so poisonous to children if inadvertently ingested, a child-proof seal should be obligatory for these products, as is currently the case for medicines.

28. Nicotine-free liquids are now available on the market, in addition to nicotine-containing products, for use in electronic cigarettes. In order to classify electronic cigarettes in a single legal field, these products should also be included in the Proposal for a Directive.
29. The liquids currently on the market contain a plethora of solutions, flavourings and additives, most of which have not been shown to be harmless to health in the event of inhalation. Analogously to the provisions of Article 5(1) of the Proposal for a Directive which apply to tobacco products ("Reporting of ingredients and emissions"), manufacturers and importers of "nicotine-containing products" should have to provide toxicological data about the ingredients used in a combusted and non-combusted form. The Directive should regulate which flavourings and additives may be added to "nicotine-containing products", as is the case for tobacco products.

Submission to the Commission

30. The Bundesrat will transmit this opinion directly to the Commission.