

## ***Information on tobacco ingredients in response to PITOC (Public Information Tobacco Control)***

### **General information about the PITOC project**

**On 13 September 2012 the German Cancer Research Centre (Deutsches Krebsforschungszentrum, DKFZ) and the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) published information and data sheets about tobacco ingredients<sup>1</sup> on their websites.**

Background to these publications is a European project called Public Information Tobacco Control (PITOC). The intention of this project was to produce readily comprehensible information for 14 tobacco ingredients by addressing their risks regarding toxicity and dependence liability. The 14 ingredients chosen for PITOC consider – in the opinion of tobacco control groups – those which carry the greatest health risk due to their chemical structure as well as those used frequently or in larger quantities.

The documents were produced independently by RIVM and DKFZ, translated into the respective languages by all parties (19 authorities and public institutions in 17 European countries) and then published on various national websites.

The PITOC documents make allegations related to ingredients. The members of the DZV wish to correct them based on existing scientific evidence.

### **Industry information on tobacco ingredients**

**Tobacco ingredients are used by manufacturers to distinguish brands in the market, to achieve taste and smell typical for the brand, and to ensure the consistent quality of the product.**

The German cigarette market is characterised by intense competition between manufacturers and their brands and products. In such a competitive market, ingredients are one way in which products can be differentiated– in addition to the tobacco blend, pack design, price, brand image, etc.

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<sup>1</sup> In this document ‘tobacco ingredients’ refer to the definition laid down in the current EU Tobacco Directive (2001/37/EC; Article 2, 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.” In certain reports, like PITOC, the term ‘ingredient’ is used interchangeable with the term ‘additive’ without any clear definition as well as scope behind.

The use of ingredients for the German cigarette market is regulated by the German Provisional Tobacco Act (Vorläufiges Tabakgesetz) and the German Tobacco Ordinance (Tabakverordnung, TVO). Many of the tobacco ingredients in use are natural or flavouring substances or extracts. Most of them are "generally recognised as safe" (GRAS) for oral ingestion including food ingredients and/or are listed on the FEMA list (Flavour and Extract Manufacturers Association). It should be emphasised that some substances in use as tobacco ingredients are already present in substantial quantities as natural constituents of the tobacco leaf; for example plant sugars and cellulose. In addition to ingredients added to tobacco, ingredients added to non-tobacco-components are in use and play a central role in the production of cigarette filters and paper. These include, for example, glues for cigarette papers and filters, filter components, and substances ensuring that the tobacco and cigarette paper burn evenly.

**Manufacturers of tobacco products are in favour of appropriate regulation of ingredients.**

Any decision to ban or regulate an ingredient should be based on sound scientific assessment appropriate for tobacco products applying validated assessment criteria. The question to look at from a consumer protection perspective is whether an ingredient increases health risks associated with smoking.

Only scientifically recognised assessment criteria for ingredients together with harmonised assessment strategies will create a reliable framework equally acceptable to all stakeholders – consumers, regulatory authorities and manufacturers.

**Under Article 6 of Directive 2001/37/EC, manufacturers and importers of tobacco products are required to disclose all ingredients in use, including available toxicological data, to the respective EU Member state competent authority on an annual basis. <sup>2</sup>**

Presently, however, there are no provisions which methods should be used for toxicological assessment or how to test whether an ingredient increases dependency and how the data can be evaluated. DZV members have therefore established their own internal product monitoring programmes for assessing ingredients. Tobacco industry scientists have published toxicological data on tobacco ingredients for many years<sup>3</sup>. The data published so far shows that the ingredients used do not increase tobacco smoke's inherent toxicity<sup>4</sup>.

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<sup>2</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>3</sup> Carmines E.L.: Evaluation of the potential effects of ingredients added to cigarettes. Part 1: cigarette design, testing approach, and review of results, Food Chem. Toxicol., 40 (2002) 77-91.  
Rodgman A.: Some Studies of the Effects of Additives on Cigarette Mainstream Smoke Properties. I. Flavorants, Beitr. Tabakforsch. Int., 20 (2002) 83-103.

Until today, the European Commission has failed to give serious consideration to the subject of scientific assessment of ingredient use for tobacco products. As far as we know, there is currently no available analysis or evaluation of all the data on ingredients that has been forwarded to the authorities. Equally, there is no suitable instrument or platform available to debate the entire body of existing scientific findings in terms of their relevance from which a suitable basis for ingredient regulation can be developed, although there are already a few evidence based testing strategies for ingredients available<sup>5</sup>.

**Ingredients neither make it easier to start smoking nor make it more difficult to stop, nor do they make the product more "attractive" to young people.**

PITOC accuses the cigarette industry of deliberately using various ingredients to increase smokers' dependency, to make cigarettes more "attractive" to young people, and to make it easier for young people to start smoking.

These allegations are in striking contradiction to the legal situation, and the reality of the market. The sale and marketing of tobacco products to young people under 18 years of age is prohibited in Germany, and similar restrictions are in place across EU member states. Furthermore, there are no scientific findings to confirm the allegation that ingredients in use have the effect of increasing dependency or could increase a possibly "addictive" effect of tobacco products. We are not aware of any reliable findings indicating that the use of ingredients influences young people's decision to start smoking.

The term "attractiveness" cannot be used for any science-based regulation of tobacco ingredients. There are no validated methods or reliable data for measuring or assessing the "attractiveness" of tobacco products resulting from ingredient use. If the European Commission is to continue considering restrictions of ingredients, any such measure must be underpinned by clear definitions and reliable scientific evidence.

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Rodgman A.: Some Studies of the Effects of Additives on Cigarette Mainstream Smoke Properties. II. Casing Materials and Humectants, Beitr. Tabakforsch. Int., 20 (2002) 279-299.

Baker R.R., Massey E.D., and Smith G.: An overview of the effects of tobacco ingredients on smoke chemistry and toxicity, Food Chem. Toxicol., 42 Suppl (2004) S53-S83.

Dempsey R., Coggins C.R., and Roemer E.: Toxicological assessment of cigarette ingredients, Regul. Toxicol. Pharmacol., (2011).

<sup>4</sup> Lee P.N., Forey B.A., Fry J.S., Hamling J.S., Hamling J.F., Sanders E.B., and Carchman R.A.: Does use of flue-cured rather than blended cigarettes affect international variation in mortality from lung cancer and COPD?, Inhal. Toxicol., 21 (2009) 404-430.

Health Behaviour in School-aged Children (HBSC) study: international report from the 2001/2002 survey. Chapter 3: Tobacco smoking – Emmanuelle Godeau, Giora Rahav and Anne Hublet.

<sup>5</sup> DIN Deutsches Institut für Normung e.V. DIN Fachbericht 133 - Toxikologische Bewertung von Zusatzstoffen für Tabakprodukte - Ein Leitfaden. - Toxicological Evaluation of Additives for Tobacco Products - A Guide 2004. CORESTA - In Vitro Toxicology Task Force: The rationale and strategy for conducting in vitro toxicology testing of tobacco smoke (May 2004).

Our position is supported by the European Commission's scientific expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR<sup>6</sup>). SCENIHR comes to the clear conclusion that no ingredient could be identified which has an "addictive" effect in itself, and that there are no indications that ingredients increase the "addictive" effect of nicotine. Regarding the contribution of ingredients to the "attractiveness" of a tobacco product, the experts are unable to draw any clear conclusions.

**Despite the existence of extensive scientific data that clearly refutes the allegations against ingredients used by the industry, they are made time and again, particularly with regard to a number of individual ingredients<sup>7</sup>.**

The PITOC documents raises similar allegations related to ingredients. The members of the DZV wish to correct them based on existing scientific evidence.

In addition, the PITOC documents mention substances which are not ingredients but present in tobacco smoke (e.g. furfural and acetaldehyde).

The understanding of DZV members, based on publically available data, concerning ammonium compounds, prune concentrate, glycerol, guar gum, carob, cocoa, liquorice, menthol, propylene glycol, sorbitol, vanillin, cellulose and sugars is laid out on the following pages.

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<sup>6</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010.

<sup>7</sup> Bates, C., Jarvis, M., and Connolly, G.: Tobacco additives. Cigarette engineering and nicotine addiction, 1999. Deutsches Krebsforschungszentrum, Heidelberg Hrsg. Erhöhte Gesundheitsgefährdung durch Zusatzstoffe in Tabakerzeugnissen – Konsequenzen für die Produktregulation, 2005. Deutsches Krebsforschungszentrum, Heidelberg Hrsg. Die Tabakindustriedokumente I: Chemische Veränderungen an Zigaretten und Tabakabhängigkeit. 3. 2005.

## ***Ammonium compounds***

### **Use for tobacco products**

According to the German Tobacco Ordinance (TVO)<sup>8</sup>, various ammonium compounds are permitted for the production of chewing tobacco and snuff.

Ammonium compounds are natural constituents of tobacco. Burley tobacco has a much higher content of ammonium compounds, at 0.3-0.4 percent by weight, than Virginia tobacco which has 0-0.03 percent by weight.

Ammonium compounds are not used by DZV members as an ingredient for the production of cigarettes.

### **Allegation**

The tobacco industry is accused that adding ammonium compounds to cigarettes

- would increase the pH value of cigarette smoke, resulting in more "freely available" nicotine in the smoke. This could increase the smoker's dependency.

### **Arguments**

**Ammonium compounds are not used by DZV members as an ingredient for the production of cigarettes.**

Despite extensive scientific discussion based on clear data, the allegations about ammonium compounds are still made time and again.

**Ammonium compounds in tobacco smoke do not increase nicotine absorption and hence smokers' dependency.**

There is no link between the quantities of ammonia found in the smoke and the pH value measured in tobacco smoke<sup>9</sup>. Tobacco smoke is an aerosol, i.e. a mixture of particulate and gaseous substances. More than 99% of the nicotine in tobacco smoke exists in particulate form<sup>10</sup>. In this particulate form, nicotine is subject to the prevailing pH value in the human body, which via various

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<sup>8</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>9</sup> Callicutt, C.H., Cox, R.H., Hsu, F., Kinser, R.D., Laffoon, S.W., Lee, P.N., Podraza, K.F., Sanders, E.B., and Seaman, J.I.: The role of ammonia in the transfer of nicotine from tobacco to mainstream smoke; Regul.Toxicol Pharmacol; 46 2006.

Rickert, W.S.: Partial Characterization of 10 "Common" Brands of American Cigarettes; Project Report for Massachusetts Department of Public Health, Labstat, Inc., Kitchener, Canada, January 30, 1997.

<sup>10</sup> Stevens, N.A., Borgerding, M.F.: GC-AED Studies of Nicotine Fate in a Burning Cigarette; Anal Chem. 1999 Jun 1;71(11):2179-85. PubMed PMID: 21662755.

physiological capabilities keeps its pH value as constant as possible<sup>11</sup>. This mechanism means that the amount of nicotine absorbed by the body is independent of the pH value of the smoke or the protonation state of the nicotine. Furthermore, it is doubtful whether the methods of measuring pH values are applicable in a non-aqueous environment such as tobacco smoke<sup>12</sup>.

A comprehensive analysis by RIVM arrives at the conclusion that the use of ammonium compounds in the production of cigarettes has no effect on the absorption of nicotine in a smoker's lungs<sup>13</sup>. In its report, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also reaches the conclusion that there is no evidence of such an effect and that it is unlikely that the addition of ammonium compounds would result in higher absorption of nicotine as a result of changing the pH value in the smoke<sup>14</sup>.

**Extensive toxicological assessments show that even the addition of ammonium compounds to tobacco would not change the biological/toxic activity of the tobacco smoke.**

Although not used as an ingredient by DZV member companies, experimental studies show that the addition of ammonium compounds changes the composition but does not increase the toxicity of cigarette smoke. Extensive toxicological studies *in vitro* and *in vivo* show that naturally occurring ammonium compounds in tobacco, but also added quantities up to 1.0% diammonium phosphate and 0.41% urea do not increase the toxicity of cigarette smoke<sup>15</sup>.

**DZV members request that all decisions on permitting, restricting or even prohibiting ingredients must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the use of ammonium compounds increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on ammonium compounds. Member companies of the DZV maintain the position that

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<sup>11</sup> Benowitz, N.L.: Nicotine pharmacology and addiction; in: Nicotine safety and toxicity, edited by N .L . Benowitz, Oxford University Press, New York, 1998,pp .3-16.

<sup>12</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 414-415 ff.

Rodgman, A.: "Smoke pH": A Review; Beitr. Tabakforsch. Int. 19/3 (2000) 117-139.

<sup>13</sup> van, Amsterdam, J., Sleijffers, A., van, Spiegel, P., Blom, R., Witte, M., van de, Kassteele, J., Blokland, M., Steerenberg, P., and Opperhuizen, A.: Effect of ammonia in cigarette tobacco on nicotine absorption in human smokers. Food Chem.Toxicol. 2011.

<sup>14</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S. 55 and S. 90.

<sup>15</sup> Stavanja, M.S., Curtin, G.M., Ayres, P.H., Bombick, E.R., Borgerding, M.F., Morgan, W.T., Garner, C.D., Pence, D.H., and Swauger, J.E.: Safety assessment of diammonium phosphate and urea used in the manufacture of cigarettes; Exp.Toxicol.Pathol.; 59 , 2008. 339 - 353.

an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

## ***Prune Juice Concentrate***

### **Use for tobacco products**

Prune or plum extracts come under "fruit, dried fruit, fruit pulp, fruit juice, concentrated fruit juice and fruit syrup" as referred to in the German Tobacco Ordinance (TVO)<sup>16</sup> and are generally permitted for the manufacture of tobacco products.

Due to their taste characteristics fruit extracts such as prune are used as flavouring agents in the production of cigarettes.

In compliance with the ingredient disclosure requirements<sup>17</sup> companies annually report the amounts of ingredients used to the competent authorities since 2002. Use levels of prune extracts reported in 2011 to EU Member States cover a range between 0.01 and 0.41% of the tobacco weight of a cigarette<sup>18</sup>.

### **Allegations**

The tobacco industry is accused that adding fruit extracts such as prune to cigarettes

- would enhance the "attractiveness" of the product and thus facilitate smoking initiation, particularly for young people. Fruit extracts are said to make the smoke taste sweet, soft and mild due of their sugar content;
- would result in the formation of acetaldehyde during combustion from which a possible reaction product is produced in the body (harmane). Harmane could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of tobacco smoke as the combustion of sugars could lead to increased levels of the toxic combustion product formaldehyde in cigarette smoke;
- would reduce the pH value ("acidity") of the smoke. As a result, the amount of "free" nicotine in cigarette smoke would be reduced, leading to increased consumption and consequently higher exposure to toxic smoke constituents.

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<sup>16</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>17</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>18</sup> Letter to DG SANCO from the European cigarette association CECCM, December 20, 2011.



## Arguments

### **Adding prune extracts at the levels used by the tobacco industry does not result in a fruity-sweet taste of tobacco smoke.**

DZV members add prune extracts in such small quantities that it does not result in a fruity-sweet taste or smell of a "plum cigarette" or sweet tobacco smoke.

**Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.** Prune extracts are added to tobacco blends in the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>19</sup>.

**The addition of fruit extracts such as prune to tobacco does not result in larger quantities of acetaldehyde in the tobacco smoke. A large number of studies clearly refute the two key claims, firstly that the addition of ingredients containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content in the tobacco smoke and the quantities of ingredients containing sugars that are applied to the tobacco<sup>20</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>21</sup>. In total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the

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<sup>19</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>20</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.

Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>21</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

blood of smokers<sup>22</sup>. The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>23</sup> or the formation of the psychoactive substance harmene from acetaldehyde in the human body. Harmene occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmene in human blood and the quantity and type of products containing harmene that are consumed<sup>24</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which prune extracts have been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of prune extracts.**

In smoke chemistry studies of cigarettes with prune extracts added in the usual quantities, no significant change in smoke composition was observed. Toxicological studies show that the addition of prune extracts in the usual quantities does not increase the biological/toxic activity of tobacco smoke<sup>25</sup>.

**The addition of sugar compounds to the tobacco of traditional American blend cigarettes does not result in any change in the amount of nicotine available to the smoker in the tobacco smoke.**

The theoretical background for this allegation is the assumption that a change in the "acidity" (pH value) of tobacco smoke will change the proportion of available nicotine in the smoke. There is no correlation between the pH value measured in the smoke and the nicotine content of tobacco smoke<sup>26</sup>.

Tobacco smoke is an aerosol, i.e. a mixture of particulate and gaseous substances. More than 99% of the nicotine in tobacco smoke exists in particulate form<sup>27</sup>. In this particulate form, nicotine is subject

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<sup>22</sup> Seeman, J.I., Doherty, M.C. and Haussmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; Chem.Res.Toxicol. 15, 2002.

<sup>23</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>24</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmene Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; Journal of Toxicology 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>25</sup> Carmines, E.L: Evaluation of the potential effects of ingredients added to cigarettes. Part 1: cigarette design, testing approach, and review of results; Food Chem.Toxicol.; 40 , 2002, 77 - 91.  
Baker, R.R., Massey, E.D., and Smith, G.: An overview of the effects of tobacco ingredients on smoke chemistry and toxicity; Food Chem.Toxicol.; 42 Suppl, 2004, S53 - S83.  
Coggins, C.R., Wagner, .KA., Werley, M.S., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: carbohydrates and natural products; Inhal.Toxicol.; 19-4-2011.

<sup>26</sup> Callicutt, C.H., Cox, R.H., Hsu, F., Kinser, R.D., Laffoon, S.W., Lee, P.N., Podraza, K.F., Sanders, E.B., and Seeman, J.I.: The role of ammonia in the transfer of nicotine from tobacco to mainstream smoke; Regul.Toxicol Pharmacol; 46. 2006.

<sup>27</sup> Stevens N.A, Borgerding M.F.: GC-AED Studies of Nicotine Fate in a Burning Cigarette. Anal Chem. 1999 Jun 1;71(11):2179-85. PubMed PMID: 21662755.

to the prevailing pH value in the human body, which via various physiological capabilities keeps its pH value as constant as possible<sup>28</sup>. This mechanism means that the amount of nicotine absorbed by the body is independent of the pH value of the smoke or the protonation state of the nicotine. Furthermore, it is doubtful whether the methods of measuring pH values are applicable in a non-aqueous environment to an aerosol such as tobacco smoke<sup>29</sup>.

**DZV members request that all decisions on permitting, restricting or even prohibiting fruit extracts, such as prune, must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients. This would include, for example, an evaluation of whether or not the addition of fruit extracts such as prune increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on fruit extracts, such as prune. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>28</sup> Benowitz, N.L.: Nicotine pharmacology and addiction; in: Nicotine safety and toxicity, edited by N .L . Benowitz, Oxford University Press, New York, 1998,pp .3-16.

<sup>29</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 414-415 ff.  
Rodgman, A.: "Smoke pH": A Review; Beitr. Tabakforsch. Int. 19 (2000) 117-139.

## **Glycerol**

### **General**

Glycerol is a component of natural fats and oils and plays a central role as an intermediate in various biological metabolic processes. It is permitted for use in food in the EU as the food additive E422 and is mainly used as a humectant and sweetener.

### **Use for tobacco products**

In Germany, the German Tobacco Ordinance (TVO)<sup>30</sup> stipulates that glycerol may be used as a humectant for smoking tobacco, cigars, cigarettes, homogenised tobacco leaf and artificial wrapper in quantities up to 5% based on tobacco dry weight, for chewing tobacco and snuff up to a maximum of 10%.

Glycerol is also a natural constituent of the tobacco leaf and is, therefore, found in finished cigarettes in levels of up to 0.4 percent by weight<sup>31</sup>.

In compliance with the ingredient disclosure requirements<sup>32</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. According to PITOC, use levels of glycerol reported in 2011 to EU Member States were on average 1% up to a maximum of 4.5% based on the tobacco weight in cigarettes.

### **Allegations**

The tobacco industry is accused that adding glycerol

- and other humectants would increase the water content of the smoke condensate and this would make the smoke taste less harsh;
- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking;
- and other humectants would increase the toxicity of the smoke because the combustion of glycerol could cause the formation of unsaturated aldehydes, such as acrolein, and alkyl epoxides (e.g. propylene oxide) in the smoke.

### **Arguments**

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<sup>30</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>31</sup> Rodgman, A.: Some studies of the effects of additives on cigarette mainstream smoke properties. II. Casing materials and humectants; Beitr. Tabakforsch. Int. 20 (2002) 279–299.

<sup>32</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

**There is no evidence that the taste of tobacco smoke becomes less harsh as a result of adding humectants, such as glycerol.**

As a result of the water-binding properties of humectants, tobacco smoke and smoke condensate are "enriched" with water. The smoke components formed during the combustion of tobacco are diluted. This is indicated in smoke chemistry analyses in the form of a significant reduction of a number of smoke components (e.g. various aldehydes, phenolic components and nitrosamines). The published *in vitro* and *in vivo* studies show that as a result of the dilution of the tobacco smoke, slightly reduced toxic effects can be observed at high doses. It is, however, not possible to draw any conclusions whether or to what extent this "dilution effect" could make the cigarette smoke taste less harsh, as there are no relevant validated and recognised test methods, and the individual human sense of taste is subjective.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes, to which glycerol has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of glycerol.**

A large proportion of the glycerol that is added to tobacco transfers unchanged to the mainstream and sidestream smoke. Pyrolysis data without tobacco, and smoke chemistry studies of cigarettes, using labelled glycerol, show that less than 1% of the glycerol used is converted into acrolein<sup>33</sup>. Even a high level of glycerol (> 5%) does not result in significantly increased amounts of acrolein in the tobacco smoke<sup>34</sup>. The addition of glycerol is more likely to result in a reduction of a number of smoke components (e.g. various aldehydes, phenolic components and nitrosamines) predominately by increasing the proportion of water in the condensate<sup>35</sup>.

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<sup>33</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of tobacco ingredients; *J & Anal & Appl & Pyrolysis*; 2004. 223 - 311.

Yip, S.H., Taylor, L.T., Ashraf-Khorassani, M., Yu, J., Borgerding, M.F., Coleman, W.M., and Bodnar, J.A.: HPLC-MS Determination of Acrolein and Acetone Generated from <sup>13</sup>C<sub>3</sub>-Labeled Glycerol Added to Cigarette Tobacco Using Two Machine-Smoking Regimes; *Beitr. Tabakforsch. Int.* 24 (2010) 48 - 57.

Purkis, S.W., Mueller, C., and Intorp, M: The fate of ingredients in and impact on cigarette smoke; *Food Chem.Toxicol.* 29-9-2011.

<sup>34</sup> Hahn, J. and Schaub, J.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke; *Beitr. Tabakforsch. Int.* 24 (2010) 100-116.

Intorp, M., Pani, J. and Blumenstock, M.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke - Additional Analysis of Three Tobacco Industry Based Laboratories; *Beitr. Tabakforsch. Int.* 24 (2010) 139-144.

Roemer, E., Wittke, S., Trelles Sticken, E., Piade, J.J., Bonk, T. and Schorp, M.K.: The Addition of Cocoa, Glycerol, and Saccharose to the Tobacco of Cigarettes: Implications for Smoke Chemistry, In Vitro Cytotoxicity, Mutagenicity and Further Endpoints; *Beitr. Tabakforsch. Int.* 24 (2010) 117-138.

<sup>35</sup> Heck, J.D., Gaworski, C.L., Rajendran, N., and Morrissey, R.L.: Toxicologic evaluation of humectants added to cigarette tobacco: 13-week smoke inhalation study of glycerin and propylene glycol in Fischer 344 rats; *Inhal.Toxicol.* 14 , 2002. 1135 - 1152.

Carmines, E.L. and Gaworski, C.L.: Toxicological evaluation of glycerin as a cigarette ingredient. *Food Chem Toxicol* 43 , 2005. 1521 - 1539.

Roemer, E., Wittke, S., Trelles Sticken, E., Piade, J.J., Bonk, T. and Schorp, M.K.: The Addition of Cocoa, Glycerol, and Saccharose to the Tobacco of Cigarettes: Implications for Smoke Chemistry, In Vitro Cytotoxicity, Mutagenicity and Further Endpoints; *Beitr. Tabakforsch. Int.* 24 (2010) 117-138.

Extensive toxicological studies *in vitro* and *in vivo* show that glycerol as a tobacco ingredient in usual quantities – but even in large amounts of 10-15% – does not increase the toxicity of cigarette smoke<sup>35</sup>. As an ingredient, glycerol changes the composition but does not increase the toxicity of cigarette smoke.

**The use of humectants such as glycerol is essential to ensure consistently high product quality during the manufacturing process and storage of the product.**

Humectants such as glycerol keep the moisture in the tobacco leaf during the production process. Therefore, they make it easier to cut the leaves and avoid production waste in the form of tobacco dust. The use of humectants is also essential with regard to product quality during the storage and sale of tobacco products.

**Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Glycerol is used by manufacturers to improve the properties of the raw material (tobacco leaf) during the manufacturing process and to ensure consistent quality during the storage and sale of the product. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>36</sup>.

**DZV members request that all decisions on permitting, restricting or even prohibiting humectants such as glycerol must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of glycerol increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on glycerol. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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Coggins, C.R., Jerome, A.M., Edmiston, J.S., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: aliphatic carbonyl compounds; *Inhal.Toxicol.*; 23 Suppl 1 , 2011. 102 - 118.

<sup>36</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.91.

## **Guar gum**

### **General**

The ground seeds of the guar plant are called guar gum. Guar gum is a polysaccharide registered for use as the food additive E412. It is often used as a thickener and emulsifier.

### **Use for tobacco products**

The German Tobacco Ordinance (TVO)<sup>37</sup> stipulates that guar gum is permitted as an adhesive or binding and thickening agent for cigars, spun tobacco including black rolling tobacco, homogenised tobacco leaf and artificial wrapper, and as glue for side seams, filter wrappers, tips and filter (tipping) paper for cigarettes.

Guar gum is used as a binder in the tobacco portion of cigarettes. It is also used in the production of cigarette paper and filter wrappers.

In compliance with the ingredient disclosure requirements<sup>38</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. According to PITOC, use levels of guar gum reported in 2011 to EU Member States were 0.6-1.8% based on the tobacco weight in cigarettes.

### **Allegations**

The tobacco industry is accused that adding guar gum to cigarettes

- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking. Guar gum extracts – because of their content of sugars – are said to make the smoke taste sweet, soft and mild;
- would produce acetaldehyde during combustion, and a possible reaction product that is produced in the body (harmaline) could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of the tobacco smoke as sugars in the combustion process in the cigarette could lead to increased formation of toxic substances such as formaldehyde, polycyclic aromatic hydrocarbons and benzene.

### **Arguments**

**The addition of guar gum to tobacco does not make the tobacco smoke taste sweet.**

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<sup>37</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>38</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

Due to its physico-chemical properties, guar gum does not transfer unchanged to the smoke of the burning cigarette while smoking. Instead, they are liable to break-down/burn under the effect of heat<sup>39</sup>. As a result, the addition of guar gum cannot make the tobacco smoke taste sweet.

**Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Various sugars are added to tobacco blends during the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the regulatory context, the term "attractiveness" is used in relation to tobacco ingredients without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>40</sup>.

**The addition of ingredients containing sugars such as guar gum does not result in larger quantities of acetaldehyde in the tobacco smoke. A large number of studies clearly refute the two key claims, firstly that the addition of ingredients containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases a smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content of the tobacco smoke and the quantities of ingredients containing sugars that are applied to the tobacco<sup>41</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>42</sup>. In total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

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<sup>39</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

<sup>40</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>41</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.  
Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>42</sup> *Tobacco: production, chemistry and technology*; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.



The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>43</sup>.

The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>44</sup> or the formation of the psychoactive substance harmene from acetaldehyde in the human body. Harmene occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmene in human blood and the quantity and type of products containing harmene that are consumed<sup>45</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which guar gum has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of guar gum.**

Extensive toxicological studies *in vitro* and *in vivo* show that guar gum as a tobacco ingredient in the usual quantities does not increase the toxicity of cigarette smoke<sup>46</sup>. As an ingredient, guar gum changes the composition but does not increase the toxicity of cigarette smoke.

**DZV members request that all decisions on permitting, restricting or even prohibiting guar gum must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of guar gum increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>43</sup> Seeman, J.I., Doherty, M.C. and Hausmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; *Chem.Res.Toxicol.* 15, 2002.

<sup>44</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>45</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmene Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; *Journal of Toxicology* 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>46</sup> Coggins, C.R., Edmiston, J.S., Jerome, A.M., Langston, T.B., Sena, E.J., Smith, D.C., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: essential oils and resins; *Inhal.Toxicol.*; 23 Suppl 1, 2011. 41 - 69.

## **Carob**

### **General**

The ground flesh of the fruit of the carob tree (E410) is similar to cocoa powder but less bitter. The powder's natural sugar content and specific flavour are comparable to those of cocoa. However, carob is lower in fat and free of substances such as caffeine and theobromine. In some cases it is used as a substitute for cocoa powder. Because of its swelling properties it is also used as a thickener.

### **Use for tobacco products**

The German Tobacco Ordinance (TVO)<sup>47</sup> stipulates that carob is permitted as an adhesive or binding and thickening agent for cigars, spun tobacco including black rolling tobacco, homogenised tobacco leaf and artificial wrapper, and as glue for side seams, filter wrappers, tips and filter (tipping) paper for cigarettes.

Carob is also used in the production of cigarette paper and cigarette filters. Owing to its taste characteristics, carob is further used as a flavouring agent in the casing process for cigarettes.

In compliance with the ingredient disclosure requirements<sup>48</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. Use levels of carob reported in 2011 to EU Member States were 0.1-0.40% based on the tobacco weight in cigarettes<sup>49</sup>.

### **Allegations**

The tobacco industry is accused that adding carob to cigarettes

- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking. Carob extracts – because of their content of sugars – are said to make the smoke taste sweet, soft and mild;
- would produce acetaldehyde during combustion, and a possible reaction product that is produced in the body (harmane) could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;

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<sup>47</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>48</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>49</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011.

- would increase the toxicity of the tobacco smoke as sugars in the combustion process in the cigarette could lead to increased formation of toxic substances such as formaldehyde, polycyclic aromatic hydrocarbons and benzene.

## Arguments

### **The addition of carob does not make the tobacco smoke taste sweet.**

Due to its physico-chemical properties, carob does not transfer unchanged to the smoke of the burning cigarette while smoking. Instead, they are liable to break-down/burn under the effect of heat<sup>50</sup>. As a result, the addition of carob cannot make the tobacco smoke taste sweet.

### **Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Carob is added to tobacco blends in the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>51</sup>.

### **The addition of ingredients containing sugars such as carob to tobacco does not result in larger quantities of acetaldehyde in the tobacco smoke. A large number of studies clearly refute the two key claims, firstly that the addition of ingredients containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content of the tobacco smoke and the quantities of ingredients containing sugars that are applied to the tobacco<sup>52</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>53</sup>. In

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<sup>50</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

<sup>51</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>52</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.

Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>54</sup>.

The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>55</sup> or the formation of the psychoactive substance harmine from acetaldehyde in the human body. Harmine occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmine in human blood and the quantity and type of products containing harmine that are consumed<sup>56</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which carob has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of carob.**

Extensive toxicological studies *in vitro* and *in vivo* show that carob as a tobacco ingredient in the usual quantities does not increase the toxicity of cigarette smoke<sup>57</sup>. As an ingredient, carob changes the composition but does not increase the toxicity of cigarette smoke.

**DZV members request that all decisions on permitting, restricting or even prohibiting carob must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for**

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<sup>53</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

<sup>54</sup> Seeman, J.I., Doherty, M.C. and Haussmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; Chem.Res.Toxicol. 15, 2002.

<sup>55</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>56</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmine Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; Journal of Toxicology 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>57</sup> Gaworski, C.L., Dozier, M.M., Heck, J.D., Gerhart, J.M., Rajendran, N., David, R.M., Brennecke, L.H., and Morrissey, R.: Toxicologic evaluation of flavor ingredients added to cigarette tobacco: 13-week inhalation exposures in rats; Inhalation Toxicology; 10, 1998. 357 - 381.

Gaworski, C.L., Heck, J.D., Bennett, M.B., and Wenk, M.L.: Toxicologic evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice; Toxicology; 139, 29-11-1999. 1 - 17.

Baker, R.R., Massey, E.D., and Smith, G.: An overview of the effects of tobacco ingredients on smoke chemistry and toxicity; Food Chem.Toxicol.; 42 Suppl, 2004, S53 - S83.

Coggins, C.R., Edmiston, J.S., Jerome, A.M., Langston, T.B., Sena, E.J., Smith, D.C., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: essential oils and resins; Inhal.Toxicol.; 23 Suppl 1, 2011. 41 - 69.

**example, an evaluation of whether or not the addition of carob increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on carob. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

## **Cocoa**

### **Use for tobacco products**

In Germany, cocoa and cocoa products are generally permitted in the German Tobacco Ordinance (TVO)<sup>58</sup> as an ingredient in the manufacture of tobacco products.

Cocoa is specifically used in the casing process in the production of traditional American blend cigarettes. Cocoa is not a single substance but a mixture of substances. A very large number of substances that are found in cocoa are also natural constituents of tobacco leaves and are therefore also found in the tobacco of finished cigarettes.

In compliance with the ingredient disclosure requirements<sup>59</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. Use levels of cocoa reported in 2011 to EU Member States were 0.66-1.16 % based on the tobacco weight in cigarettes<sup>60</sup>.

### **Allegations**

The tobacco industry is accused that adding cocoa to cigarettes

- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking. Cocoa is said to make the tobacco smoke taste like chocolate;
- would result in increased absorption of nicotine and hence in stronger dependence of the smoker caused by the bronchodilating effect of pharmacologically active substances in cocoa;
- would produce acetaldehyde during combustion, and a possible reaction product that is produced in the body (harmane) could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of the smoke because the bronchodilating effect also means that larger quantities of harmful smoke may be absorbed by the smoker.

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<sup>58</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>59</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>60</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011.

## Arguments

### **The addition of cocoa does not make the tobacco smoke taste sweet or like chocolate.**

Due to its physico-chemical properties, cocoa does not transfer unchanged to the smoke while smoking. Instead, they are liable to break-down/burn under the effect of heat<sup>61</sup>. As a result, the addition of cocoa cannot make the tobacco smoke taste like chocolate.

### **Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Cocoa and cocoa products are added to tobacco blends during the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>62</sup>.

### **Scientific findings demonstrate that cocoa as an ingredient has no bronchodilatory effect; it does not increase smoker`s dependency.**

Raw cocoa naturally contains a multitude of different substances, including pharmacologically active substances such as theobromine (approx. 1-2.5%). Theobromine is a metabolite of caffeine and in experiments shows a weak bronchodilating effect.

Based on modelling and a comprehensive analysis, RIVM's own work concludes that the smoker's exposure to pharmacologically active components from the cocoa present in cigarette tobacco is negligible. The decomposition products of cocoa resulting from combustion and their concentrations in cigarette smoke also have no pharmacologically relevant activity spectrum<sup>63</sup>. The amounts absorbed when smoking cigarettes are too low to have any local effect in the respiratory tract. Hence the addition of cocoa to the tobacco has no bronchodilating effect and hence no dependency-increasing effect when smoking.

### **The addition of cocoa to tobacco does not result in larger quantities of acetaldehyde in the tobacco smoke. Extensive data clearly refutes the two key claims, firstly that the addition of substances containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

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<sup>61</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

<sup>62</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>63</sup> Rambali, B., van Andel, I., Schenk, E., Wolterink, van de Werken, G., Stevenson, H., and Vleeming, W.: *The contribution of cocoa additive to cigarette smoking addiction*. 2002.

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content of tobacco smoke and the quantities of cocoa applied to the tobacco<sup>64</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>65</sup>. In total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>66</sup>.

The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>67</sup> or the formation of the psychoactive substance harmine from acetaldehyde in the human body. Harmine occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmine in human blood and the quantity and type of products containing harmine that are consumed<sup>68</sup>.

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<sup>64</sup> Torikai, K., Uwano, Y., Nakamori, T., Tarora, W., and Takahashi, H.: Study on tobacco components involved in the pyrolytic generation of selected smoke constituents; *Food Chem.Toxicol.*; 43 , 2005. 559 - 568.

Hahn, J. and Schaub, J.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke; *Beitr. Tabakforsch. Int.* 24 (2010) 100-116.

Intorp, M., Pani, J. and Blumenstock, M.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke - Additional Analysis of Three Tobacco Industry Based Laboratories; *Beitr. Tabakforsch. Int.* 24 (2010) 139-144.

Roemer, E., Wittke, S., Trelles Sticken, E., Piade, J.J., Bonk, T. and Schorp, M.K.: The Addition of Cocoa, Glycerol, and Saccharose to the Tobacco of Cigarettes: Implications for Smoke Chemistry, In Vitro Cytotoxicity, Mutagenicity and Further Endpoints; *Beitr. Tabakforsch. Int.* 24 (2010) 117-138.

<sup>65</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

<sup>66</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.

Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>67</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>68</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmine Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; *Journal of Toxicology* 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.



**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which cocoa has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of cocoa.**

Extensive toxicological studies *in vitro* and *in vivo* show that cocoa as a tobacco ingredient in the usual or even significantly higher quantities (of up to 5%) does not increase the toxicity of cigarette smoke. As an ingredient, cocoa changes the composition but does not increase the toxicity of cigarette smoke<sup>69</sup>.

**The addition of cocoa and cocoa products to tobacco is necessary for the production of traditional American blend products in order to achieve the characteristic taste of these products and to differentiate the product in a competitive market.**

Most of the substances found in cocoa are also natural constituents of tobacco leaves<sup>70</sup>. Especially in the case of Burley tobacco, the slow drying process changes its chemical composition. Drying causes Burley tobacco to lose almost all sugar compounds. To compensate for the loss, the substances which were partially lost are replenished in the Burley tobacco in the casing process by adding cocoa and cocoa products.

**DZV members request that all decisions on permitting, restricting or even prohibiting cocoa as an ingredient must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of cocoa increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of various ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on cocoa. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>69</sup> Coggins, C.R., Fisher, M.T., Smith, D.C., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: cocoa-derived ingredients; *Inhal.Toxicol.*; 23 Suppl 1, 2011. 70 - 83.

Hahn, J. and Schaub, J.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke; *Beitr. Tabakforsch. Int.* 24 (2010) 100-116.

Intorp, M., Pani, J. and Blumenstock, M.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke - Additional Analysis of Three Tobacco Industry Based Laboratories; *Beitr. Tabakforsch. Int.* 24 (2010) 139-144.

Roemer, E., Wittke, S., Trelles Sticken, E., Piade, J.J., Bonk, T. and Schorp, M.K.: The Addition of Cocoa, Glycerol, and Saccharose to the Tobacco of Cigarettes: Implications for Smoke Chemistry, In Vitro Cytotoxicity, Mutagenicity and Further Endpoints; *Beitr. Tabakforsch. Int.* 24 (2010) 117-138.

<sup>70</sup> Harllee, G.C. and Leffingwell, J.C.: Casing materials – cocoa (Part III), *Tobacco International* 181 (6), March 23, pp 18 – 43.

## **Liquorice**

### **General**

Liquorice extracts are produced from dried roots of the liquorice plant, which is found mainly in the Mediterranean region. A natural constituent of liquorice root extract is glycyrrhizin. Glycyrrhizic acid, which is released by degradation of glycyrrhizin, inhibits a key enzyme in the body's hormonally controlled mineral balance. Repeatedly ingesting larger quantities of glycyrrhizin may provoke changes in the body's mineral status. The consequences are raised blood pressure, fluid retention (oedema) and muscle weakness. Hence for a number of years it has been recommended that the ingestion of glycyrrhizin should be kept below 100 mg per day<sup>71</sup>.

### **Use for tobacco products**

According to the German Tobacco Ordinance (TVO)<sup>72</sup> liquorice is permitted as an ingredient for the manufacture of tobacco products.

Liquorice and liquorice extracts are used as flavouring agents and humectants specifically in the casing process for American blend cigarettes. A large number of substances naturally present in liquorice extracts are also constituents of tobacco leaves and are therefore found in cigarette tobacco.

In compliance with the ingredient disclosure requirements<sup>73</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. Use levels of liquorice and liquorice extracts reported in 2011 to EU Member States cover a range between 0.7 and 1.07% of the tobacco weight of a cigarette<sup>74</sup>.

### **Allegations**

The tobacco industry is accused that adding liquorice to cigarettes

- would enhance the "attractiveness" of the product and thus facilitates smoking initiation, particularly for young people. Liquorice is said to make the smoke taste sweet;

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<sup>71</sup>[http://www.dfg.de/download/pdf/dfg\\_im\\_profil/reden\\_stellungnahmen/2004/sklm\\_glycyrrhizin\\_2004.pdf](http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2004/sklm_glycyrrhizin_2004.pdf).

<sup>72</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>73</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>74</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011.

- would result in increased absorption of nicotine and hence in stronger dependence of the smoker caused by the bronchodilating effect of the pharmacologically active substance glycyrrhizin;
- would result in the formation of acetaldehyde during combustion from which a possible reaction product is produced in the body (harmane). Harmane could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of tobacco smoke. As a result of the bronchodilating effect, larger quantities of harmful smoke may be absorbed by the smoker.

## **Arguments**

### **Adding liquorice extracts does not result in a sweet taste of tobacco smoke.**

Due to its physico-chemical properties, liquorice extract added to tobacco does not transfer unchanged to the smoke. Instead, they are liable to break-down/burn and decompose under the effect of heat<sup>75</sup>. As a result, the addition of liquorice extract cannot make the tobacco smoke taste sweet.

### **There are no scientific findings demonstrating that liquorice extracts added to tobacco have a bronchodilating effect and increase "addictiveness".**

Glycyrrhizin is not added as such, but it is a natural constituent of liquorice extracts. Available data on the fate of liquorice constituents in tobacco during smoking is insufficient. However, an assessment carried out by RIVM allows the conclusion that the small amounts of glycyrrhizin present in the added liquorice extracts<sup>76</sup> do not result in an increased health risk or increased dependency of the smoker<sup>77</sup>.

### **Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Liquorice extracts are added to tobacco blends in the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks,

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<sup>75</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

<sup>76</sup> Tobacco of American-Blend-Cigarettes contains app. 0,311 mg Glycyrrhizin / Cigarette (Rickert, W.S.: Partial characterization of 10 'common' brands of American cigarettes; Project Report prepared for the Massachusetts Department of Public Health, Labstat, Inc., Kitchener, ON, J anuary 30, 1997.).

<sup>77</sup> van Andel, I., Wolterink, G., van de Werken, G., Stevenson, H., van Aerts, L.A.G.J.M., and Vleeming, W.: The health and addiction risk of the glycyrrhizic acid component of liquorice root used in tobacco products. 2003.

SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>78</sup>.

**The addition of liquorice extracts to tobacco does not result in larger quantities of acetaldehyde in the tobacco smoke. Extensive data clearly refutes the two key claims, firstly that the addition of substances containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content in tobacco smoke and the quantities of substances containing sugars that are applied to the tobacco<sup>79</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>80</sup>. In total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>81</sup>.

The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>82</sup> or the formation of the psychoactive substance harmine from acetaldehyde in the human body. Harmine occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that

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<sup>78</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>79</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.  
Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>80</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

<sup>81</sup> Seeman, J.I., Doherty, M.C. and Haussmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; *Chem.Res.Toxicol.* 15, 2002.

<sup>82</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

there is no correlation between the amount of harmene in human blood and the quantity and type of products containing harmene that are consumed<sup>83</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which liquorice extracts have been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of liquorice extracts.**

Extensive toxicological studies *in vitro* and *in vivo* show that liquorice extracts as a tobacco ingredient in the usual quantities do not increase the toxicity of cigarette smoke. As an ingredient, liquorice extracts change the composition but do not increase the toxicity of cigarette smoke<sup>84</sup>.

**The addition of liquorice extracts to tobacco is necessary for the production of traditional American blend products in order to achieve the characteristic taste of these products and to differentiate the product in a competitive market.**

Most of the substances found in liquorice extracts are also natural constituents of tobacco leaves<sup>85</sup>. Especially in the case of Burley tobacco, the slow drying process changes its chemical composition. Drying causes Burley tobacco to lose almost all sugar compounds. To compensate for the loss, the substances which were partially lost are replenished in the Burley tobacco in the casing process by adding liquorice extracts.

**DZV members request that all decisions on permitting, restricting or even prohibiting liquorice extracts must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of liquorice extracts increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on liquorice extracts. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>83</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmene Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; *Journal of Toxicology* 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>84</sup> Carmines, E.L., Lemus, R., and Gaworski, C.L.: Toxicologic evaluation of licorice extract as a cigarette ingredient; *Food Chem.Toxicol.*; 43 , 2005. 1303 - 1322.

<sup>85</sup> Schumacher, J.N., Colby, D.A., and Shelar, G.L.: A literature study of liquorice; *RDM*, 1981, No. 10, March 16 (INT-500609291-9317).

## ***Menthol***

### **General**

Menthol is the main constituent of peppermint oil. It is produced synthetically or derived from the Japanese mint plant. Specific receptors in the body are mainly responsible for the typical cooling sensation associated with menthol.

### **Use in tobacco products**

Menthol is permitted for use as a flavouring for tobacco products according to the German Tobacco Ordinance (TVO)<sup>86</sup>. In compliance with the ingredient disclosure requirements<sup>87</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. Use levels of menthol reported in 2011 to EU Member States were 0.45% on average up to a maximum of 1.67% of the tobacco weight of a cigarette<sup>88</sup>.

### **Allegations**

The tobacco industry is accused that menthol in cigarettes

- would act as "softening agent" to make it easier for people to start smoking, and would influence inhalation depth and therefore promote "addictiveness";
- would increase health risks associated with smoking;
- would be added to virtually all brands in subliminal quantities.

### **Arguments**

**None of the available scientific data or findings show that the consumption of menthol cigarettes is associated with deeper inhalation of mainstream smoke or increased "addictiveness" compared to non-menthol cigarettes.**

There is a large amount of scientific data and findings available on menthol as a tobacco ingredient.

The scientific data demonstrate:

- Consumers of menthol cigarettes do not inhale smoke more intensely ("inhalation depth")<sup>89</sup>.

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<sup>86</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>87</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>88</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011.

<sup>89</sup> Nil, R., Battig, K.: Separate effects of cigarette smoke yield and smoke taste on smoking behavior; Psychopharmacology (1989) 99, 54–59.

- Consumers of menthol cigarettes are not exposed to a higher amount of nicotine or other toxic smoke constituents<sup>90</sup>.
- Menthol cigarette smokers do not consume more cigarettes compared to smokers of non-menthol cigarettes<sup>91</sup>.
- Menthol cigarettes do not lead to increased addiction in adults (probability and "severity")<sup>92</sup>.
- Menthol cigarettes are not associated with lowering the age of starting to smoke<sup>93</sup>.

**There is no scientific basis which suggests that smoking menthol cigarettes is associated with greater health risks than smoking non-menthol cigarettes.**

Due to its high volatility, nearly all menthol added to combustible tobacco products transfers unchanged into smoke<sup>94</sup>. Extensive toxicological studies (*in vitro* and *in vivo*) indicate that adding menthol to cigarette tobacco does not lead to higher overall toxicity of cigarette smoke in comparison to non-menthol cigarettes with the same product characteristics (filter, tobacco)<sup>95</sup>.

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Jarvik, M.E., Tashkin, D.P., Caskey, N.H., McCarthy, W.J., Rosenblatt, M.R.: Mentholated cigarettes decrease puff volume of smoke and increase carbon monoxide absorption; *Physiology and Behavior* (1994) 56, 563–570.  
 Ahijevych, K., Gillespie, J., Demirci, M., Jagadeesh, J.: Menthol and nonmenthol cigarettes and smoke exposure in black and white women; *Pharmacology Biochemistry and Behavior* (1996) 53, 355–360.  
 Ahijevych, K., Parsley, L.A.: Smoke constituent exposure and stage of change in black and white women cigarette smokers; *Addictive Behaviors* (1999) 24, 115– 120.

<sup>90</sup> Muscat, J.E., Chen G., Knipe, A. Stellman S.D., Lazarus P., and Richie J.P. Jr.: Effects of Menthol on Tobacco Smoke Exposure, Nicotine Dependence, and NNAL Glucuronidation; *Cancer Epidemiol Biomarkers Prev* (2009) 18:35-41.  
 Tobacco Products Scientific Advisory Committee (TPSAC): “Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011”.  
 Heck, J.D.: Smokers of menthol and nonmenthol cigarettes exhibit similar levels of biomarkers of smoke exposure. *Cancer Epidemiol Biomarkers Prev* (2009) 18 (2), 622–629.

<sup>91</sup> Blot, W.J., Cohen, S.S., Aldrich, M., McLaughlin, J.K., Hargreaves, M.K., and Signorello, L.B.: Lung Cancer Risk among Smokers of Menthol Cigarettes; *J Natl Cancer Inst* 2011 May 18; 103(10):810-6.

<sup>92</sup> Tobacco Products Scientific Advisory Committee (TPSAC): “Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations” 2011.  
 Muscat, J.E., Liu, A., Stellman, S.D., Richie, J.P. Jr.: Menthol smoking in relation to time to first cigarette and cotinine: Results from a community-based study; *Regul Toxicol Pharmacol.* 2012 Jun;63(1):166-70.

<sup>93</sup> Fernander, A., Rayens, M.K., Zhang, M., and Adkins, S.: Are age of smoking initiation and purchasing patterns associated with menthol smoking?; *Addiction*, (2011) 105 (Suppl. 1), 39–45.  
 American Council on Science and Health (Spring 2010): “The Mentholation of Cigarettes: A Position Statement of The American Council on Science and Health”.  
 Rising, J. and Wasson-Blader, K.: Menthol and initiation of cigarette smoking; *Tobacco Induced Diseases* 2011, 9(Suppl 1):S4.

<sup>94</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of tobacco ingredients; *J & Anal & Appl & Pyrolysis*; 2004. 223 - 311.

<sup>95</sup> Heck, J.D.: A review and assessment of menthol employed as a cigarette flavoring ingredient. *Food Chem Toxicol.*; (2010) 48 Suppl 2, S1 - 38.

Menthol as a tobacco ingredient in mentholated cigarettes does not contribute to an increased risk of lung cancer<sup>96</sup>. A recent study from the U.S. indicates the opposite: it concludes that smokers consuming menthol cigarettes may even have a lower lung cancer risk<sup>97</sup>.

**Menthol is used as a flavouring in menthol cigarettes, hence these are always referred to as "menthol cigarettes".**

**Certain flavour mixtures used to manufacture traditional (American blend) cigarettes marketed in Germany may contain small quantities of menthol. However, these amounts are too low to be sensorially detected by the consumer and they do not have any physiological effect. Accordingly, these cigarettes are not marketed as menthol cigarettes.**

The allegation that menthol is added in small quantities to nearly all tobacco products on the German and other European markets is not correct. This allegation is based on repeatedly used quotations from published studies that either do not relate to Europe at all or are based on an insufficient data set<sup>98</sup>.

Flavour mixtures containing very low quantities of menthol (parts per million or less) are not classified as menthol flavourings due to their low menthol content. The presence of menthol in such small quantities has no pharmacological effect, particularly no cooling effect.

**The debate and accusations surrounding the use of menthol as an ingredient in tobacco products seem to be inappropriate and unfounded in view of the scientific facts and consumer data, particularly in Germany. The scientific facts as well as (national) consumer data do not support the allegations that are said to be associated with the presence of menthol in cigarettes.**

In view of the scientific facts, in the opinion of DZV members it is clear that stricter regulation of menthol as an ingredient in tobacco will not contribute to the prevention of underage smoking. Other measures already introduced, however, such as age restrictions at point of sale and regarding access to cigarette vending machines, are indeed effective in preventing under-age smoking.

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<sup>96</sup> Blot, W.J., Cohen, S.S., Aldrich, M., McLaughlin, J.K., Hargreaves, M.K., and Signorello, L.B.: Lung Cancer Risk among Smokers of Menthol Cigarettes; J Natl Cancer Inst 2011 May 18;103(10):810-6.

<sup>97</sup> Rostron, B.: Lung Cancer Mortality Risk for U.S. Menthol Cigarette Smokers; Nicotine and Tobacco Research (2012).

<sup>98</sup> Deutsches Krebsforschungszentrum, Heidelberg Hrsg: Die Tabakindustriedokumente I: Chemische Veränderungen an Zigaretten und Tabakabhängigkeit, 2005.  
Kahnert, S., Nair, U., Mons, U., Pötschke-Langer, M.: Wirkungen von Menthol als Zusatzstoff in Tabakprodukten und die Notwendigkeit einer Regulierung; Bundesgesundheitsblatt 2012; 55:409–415.  
Giovino, G.A., Sidney, S., Gfroerer, J.C, O'Malley P.M., Allen J.A., Richter P.A., Cummings, K.M.: Epidemiology of menthol cigarette use. Nicotine Tob Res (2004) 6(Suppl 1):67–81: "In most other brands, however, the amount of menthol is so low (approximately 0.03% of the tobacco weight) that the mint flavor and cooling sensations are not perceptible." [0,03% ≈ 0,21 mg bei 700 mg Tabakgewicht].  
Merckel, C. and Pragst, F.: Tobacco additives in cigarettes - Intended purpose and potential of danger -- Tabakzusatzstoffe in Zigaretten - Verwendungszweck und Gefahrenpotential. Journal für Verbraucherschutz und Lebensmittelsicherheit-Journal of consumer protection and food safety; 2 , 1-8-2007. 287 - 301.



**Market trends and consumer profiles show preferences for certain cigarette types, such as menthol cigarettes. These preferences are based on cultural differences which are country specific and primarily driven by individual taste profiles.**

**If menthol made cigarette smoke more pleasant for consumers, menthol cigarettes would have a far larger share of the global cigarette market. Additionally, differences observed in consumer preference for menthol cigarettes across various markets would not vary as much as they do.**

Much of the discussion about menthol in tobacco products is rooted in the U.S. which has a firmly established menthol market (about 28-34% market share<sup>99</sup>), and may be related to the fact that about 75% of all Afro-American smokers prefer menthol cigarettes.

The market share of menthol cigarettes varies considerably in various European and other non-European countries (e.g. Great Britain: approx. 7%<sup>4</sup>; Poland: approx. 17%<sup>4</sup>; Finland: approx. 24%<sup>100</sup>; Canada: approx. 2%<sup>101</sup>; the Philippines have the largest proportion of menthol smokers worldwide with approx. 60%<sup>102</sup>).

By contrast, in Germany the market share of menthol cigarettes has remained for decades at a stable and low level of less than 3%<sup>103</sup>. The vast majority of smokers in Germany prefer non-menthol cigarettes. According to industry data regarding consumer behaviour and market share, menthol cigarettes cannot be considered as typical products initiating smoking amongst young adults in Germany.

**DZV members request that all decisions on permitting, restricting or even prohibiting ingredients must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not menthol increases the risks associated with smoking, and whether or not any restriction or prohibition of an ingredient reduces the risks associated with smoking.**

Unfortunately, much of the data and findings on the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on menthol. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>99</sup> US Food and Drug Administration's (FDA) Tobacco Products Scientific Advisory Committee (TPSAC): Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011, p 35ff.

<sup>100</sup> Representative consumer study of British American Tobacco (Germany), 2011.

<sup>101</sup> „Health Canada“: [http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/federal/amend\\_faq-modif-eng.php#q7](http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/federal/amend_faq-modif-eng.php#q7).

<sup>102</sup> Giovino, G.A., Sidney, S., Gfroerer, J.C, O'Malley P.M., Allen J.A., Richter P.A., Cummings, K.M.: Epidemiology of menthol cigarette use. Nicotine Tob Res. 2004 Feb; 6 Suppl1:S67-81.

<sup>103</sup> Deutsches Krebsforschungszentrum, Heidelberg: Kahnert, S., Nair, U., Mons, U., Pötschke-Langer, M.: Wirkungen von Menthol als Zusatzstoff in Tabakprodukten und die Notwendigkeit einer Regulierung; Bundesgesundheitsblatt 2012; 55:409–415.

## ***Propylene glycol***

### **General**

Propylene glycol is manufactured industrially by the hydrolysis of propylene oxide but it can also be produced from glycerol. Propylene glycol is used in solvents and as a humectant in hygiene products such as skin creams, toothpastes and deodorants. It can significantly improve the solubility of various substances and ensure a more stable dispersion, for example of drugs in ointments. Due to its anti-microbial effect, it is often unnecessary to add other preservatives. Propylene glycol is permitted as a food additive in the EU and is coded E1520.

### **Use for tobacco products**

In Germany, the German Tobacco Ordinance (TVO)<sup>104</sup> stipulates that propylene glycol may be used as a humectant for smoking tobacco, cigars, cigarettes and homogenised tobacco leaf in quantities up to 5% based on tobacco dry weight.

In compliance with the ingredient disclosure requirements<sup>105</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. According to PITOC, use levels of propylene glycol reported in 2011 to EU Member States were on average 1.3% up to a maximum of 5% based on the tobacco weight in cigarettes.

### **Allegations**

The tobacco industry is accused that adding propylene glycol (and other humectants) to cigarettes

- would increase the water content of the smoke condensate and this would make the smoke taste less harsh;
- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking;
- would increase the toxicity of the smoke because the combustion of propylene glycol could cause the formation of unsaturated aldehydes, such as acrolein, and alkyl epoxides (e.g. propylene oxide) in the smoke.

### **Arguments**

**There is no evidence that the taste of tobacco smoke becomes less harsh as a result of adding humectants, such as propylene glycol.**

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<sup>104</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>105</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

As a result of the water-binding properties of humectants, tobacco smoke and smoke condensate are "enriched" with water. The smoke components that form during the combustion of tobacco are kind of diluted. It is, however, not possible to draw any conclusion whether or to what extent this "dilution effect" could make the cigarette smoke taste less harsh, as there are no relevant validated and recognised test methods, and the individual human sense of taste is subjective.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes, to which propylene glycol has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of propylene glycol.**

Pyrolysis data without tobacco, and smoke chemistry studies of cigarettes show that a large proportion of the propylene glycol (95%) added to the tobacco transfers unchanged to the mainstream and sidestream smoke<sup>106</sup>. Even a high level of propylene glycol (> 10%) does not result in significantly increased amounts of propylene oxide in the tobacco smoke<sup>107</sup>.

Extensive toxicological studies *in vitro* and *in vivo* show that propylene glycol as a tobacco ingredient in the usual quantities does not increase the toxicity of cigarette smoke. As an ingredient, propylene glycol changes the composition but does not increase the toxicity of cigarette smoke.

**The use of humectants such as propylene glycol is essential to ensure consistently high product quality during the manufacturing process and storage of the product.**

Humectants such as propylene glycol keep the moisture in the tobacco leaf during the production process. Therefore, they make it easier to cut the leaves and avoid production waste in the form of tobacco dust. The use of humectants is also essential with regard to product quality during the storage and sale of tobacco products.

**Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Propylene glycol is used by manufacturers to improve the properties of the raw material (tobacco leaf) during the manufacturing process and to ensure consistent quality during the storage and sale of the product. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>108</sup>.

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<sup>106</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

Purkis, SW, Mueller, C, and Intorp, M: The fate of ingredients in and impact on cigarette smoke; *Food Chem.Toxicol.* 29-9-2011.

<sup>107</sup> Heck, J.D., Gaworski, C.L., Rajendran, N., and Morrissey, R.L.: Toxicologic evaluation of humectants added to cigarette tobacco: 13-week smoke inhalation study of glycerin and propylene glycol in Fischer 344 rats; *Inhal.Toxicol.* 14, 2002. 1135 - 1152.

Gaworski, C.L., Oldham, M.J., and Coggins, C.R.: Toxicological considerations on the use of propylene glycol as a humectant in cigarettes. *Toxicology*; 16-1-2010.

**DZV members request that all decisions on permitting, restricting or even prohibiting humectants such as propylene glycol must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of propylene glycol increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on propylene glycol. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>108</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.91.

## **Sorbitol**

### **General**

Sorbitol (E420) is used in industrially produced foods as a sugar substitute, carrier and humectant. Sorbitol occurs naturally in fruits and particularly in some pomaceous fruit varieties. Industrial production uses corn starch and wheat starch.

### **Use for tobacco products**

Sorbitol comes under "hydrogenated glucose syrup" as mentioned in the German Tobacco Ordinance (TVO)<sup>109</sup> and is generally permitted as a humectant for cigarettes, cigars, spun tobacco including black rolling tobacco, homogenised tobacco leaf and artificial wrapper.

In compliance with the ingredient disclosure requirements<sup>110</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. According to PITOC, use levels of sorbitol reported in 2011 to EU Member States were 0.044% on average up to a maximum of 0.313% based on the tobacco weight of a cigarette.

### **Allegations**

The tobacco industry is accused that adding sorbitol to cigarettes

- would - similarly to other humectants - increase the water content of smoke condensate and this would make the smoke taste less harsh;
- would enhance the "attractiveness" of the product by making the tobacco smoke taste less harsh, and sweet. This would facilitate smoking initiation, particularly for young people;
- would result in the formation of acetaldehyde during combustion from which a possible reaction product is produced in the body (harmane). Harmane could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of tobacco smoke as the combustion could lead to increased levels of the toxic combustion product formaldehyde in cigarette smoke.

### **Arguments**

**Addition of sorbitol does not result in a sweet taste of tobacco smoke.**

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<sup>109</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>110</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

Due to its physico-chemical properties, sorbitol added to tobacco does not transfer unchanged to the smoke. Instead, they are liable to break-down/burn under the effect of heat<sup>111</sup>. As a result, the addition of sorbitol cannot make the tobacco smoke taste sweet.

**There is no evidence that the taste of tobacco smoke becomes less harsh as a result of adding humectants, such as sorbitol.**

As a result of the water-binding properties of humectants, tobacco smoke and smoke condensate are "enriched" with water. The smoke components that are formed during the combustion of tobacco are kind of diluted. It is, however, not possible to draw any conclusion whether or to what extent this "dilution effect" could make the cigarette smoke taste less harsh, as there are no relevant validated and recognised test methods and the individual human sense of taste is subjective.

**Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Various sugars are added to tobacco blends during the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the regulatory context, the term "attractiveness" is used in relation to tobacco ingredients without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>112</sup>.

**The addition of ingredients to tobacco that contain sugars, such as sorbitol, does not result in larger quantities of acetaldehyde in the tobacco smoke. A large number of studies clearly refute the two key claims, firstly that the addition of ingredients containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content of tobacco smoke and the quantities of ingredients containing sugars that are applied to the tobacco<sup>113</sup>.

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<sup>111</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

<sup>112</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>113</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.

Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>114</sup>. In total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>115</sup>.

The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>116</sup> or the formation of the psychoactive substance harmine from acetaldehyde in the human body. Harmine occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmine in human blood and the quantity and type of products containing harmine that are consumed<sup>117</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which sorbitol has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of sorbitol.**

Particularly due to its hygroscopic properties, adding sorbitol results in the dilution of the smoke condensate and hence reduces the levels of a number of smoke components such as nitrosamines and nicotine. Sorbitol in quantities typically added to cigarette tobacco does not result in an increased amount of formaldehyde in tobacco smoke<sup>10</sup>.

Extensive toxicological studies *in vitro* and *in vivo* show that sorbitol as a tobacco ingredient in the usual quantities does not increase the toxicity of cigarette smoke<sup>118</sup>. As an ingredient, sorbitol changes the composition but does not increase the toxicity of cigarette smoke.

**The use of humectants such as sorbitol is necessary to ensure consistently high product quality during the manufacture and storage of the product.**

Humectants such as sorbitol keep the moisture in the tobacco leaf during the production process. Therefore, they make it easier to cut the leaves and avoid production waste in the form of tobacco

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<sup>114</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

<sup>115</sup> Seeman, J.I., Doherty, M.C. and Hausmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; Chem.Res.Toxicol. 15, 2002.

<sup>116</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>117</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmine Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; Journal of Toxicology 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>118</sup> Baker, R.R., Massey, E.D., and Smith, G.: An overview of the effects of tobacco ingredients on smoke chemistry and toxicity; Food Chem.Toxicol.; 42 Suppl, 2004, S53 - S83.  
Coggins, C.R., Wagner, .KA., Werley, M.S., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: carbohydrates and natural products; Inhal.Toxicol.; 19-4-2011.

dust. The use of humectants is also essential with regard to product quality during the storage and sale of tobacco products.

**DZV members request that all decisions on permitting, restricting or even prohibiting sorbitol must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of sorbitol increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on sorbitol. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.



## **Vanillin**

### **General**

Vanillin is the main flavouring substance in the capsules of the vanilla plant, and also a nature-identical flavouring agent. By quantity, vanilla is the most important flavouring agent world-wide and used in food, drinks, ice cream, bakery products and chocolates, as well as by the fragrance and pharmaceutical industries.

### **Use for tobacco products**

According to the German Tobacco Ordinance (TVO)<sup>119</sup>, vanillin can be added as flavouring to tobacco (in accordance with the German Flavourings Ordinance (Aromenverordnung, AromV) in the version of 2 May 2006).

Due to its taste characteristics, vanillin may be a component of flavour mixtures for the manufacture of tobacco products.

In compliance with the ingredient disclosure requirements<sup>120</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. Use levels of vanillin reported in 2011 to EU Member States were 0.04-0.09% based on the tobacco weight per cigarette<sup>121</sup>.

### **Allegations**

The tobacco industry is accused that adding vanillin to cigarettes

- would enhance the "attractiveness" of the product, which could make it easier for young consumers in particular to start smoking;
- would increase the toxicity of the tobacco smoke as polycyclic aromatic hydrocarbons (PAH) are formed during the combustion of vanillin.

### **Arguments**

#### **Adding vanillin at low levels does not result in a vanilla-like taste of tobacco smoke.**

The member companies of the DZV add vanillin in such small quantities that it does not result in the taste or smell of a "vanilla cigarette".

#### **Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for**

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<sup>119</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>120</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>121</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011.

**the scientifically based regulation of tobacco ingredients.** Vanillin is added to tobacco blends in the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the context of regulating tobacco ingredients, the term "attractiveness" is used without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>122</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which vanillin has been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of vanillin.**

Vanillin in the tobacco is not thermally degraded by the combustion/pyrolysis processes in a cigarette, and a portion of the added vanillin transfers unchanged to the tobacco smoke<sup>123</sup>. Extensive toxicological studies *in vitro* and *in vivo* show that vanillin as a tobacco ingredient in the usual quantities does not increase the toxicity of cigarette smoke<sup>124</sup>. As an ingredient, vanillin changes the composition but does not increase the toxicity of cigarette smoke.

**DZV members request that all decisions on permitting, restricting or even prohibiting vanillin must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of vanillin increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on vanillin. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>122</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>123</sup> Green J.D., Chalmers J., Kinnard, P.J.: The Transfer of Tobacco Additives to Cigarette Smoke: Examination of the Possible Contribution of Pyrolysis Products to Mainstream Smoke Composition; Beitr. Tabakforsch. Int. 14/5 (1989) 283-288.

Baker, R.R. and Bishop, L.J.: The pyrolysis of tobacco ingredients; J & Anal & Appl & Pyrolysis; 2004. 223 - 311.  
Stotesbury, S., Willoughby, .L.J. and Couch, A.: Pyrolysis of Cigarette Ingredients Labelled with Stable Isotopes; Beitr. Tabakforsch. Int. 19 (2000) 55 - 64.

Purkis, S.W., Mueller, C., and Intorp, M.: The fate of ingredients in and impact on cigarette smoke; Food Chem.Toxicol. 29-9-2011.

<sup>124</sup> Lemus, R., Carmines, E.L., Van, Miert, E., Coggins, C.R., Anskeit, E., Gerstenberg, B., Meisgen, T.J., Schramke, H., Stabbert, R., Volk, H., and Terpstra, P.M.: Toxicological comparisons of cigarettes containing different amounts of vanillin; Inhal.Toxicol.; 19, 2007. 683 - 699.

Coggins, C.R., Sena, E.J., Langston, T.B., and Oldham, M.J.: A comprehensive evaluation of the toxicology of cigarette ingredients: aromatic carbonyl compounds; Inhal.Toxicol.; 23 Suppl 1, 2011. 90 - 101.

## **Cellulose**

### **General**

Cellulose is the main constituent of plant cell walls (around 50% of their dry mass) and hence the most common naturally occurring organic material. Cellulose is an important raw material for paper manufacturing, but cellulose and cellulose derivatives are also used by the food and pharmaceutical industries as thickening agents, carrier, filler and anti-caking agents. As food additive, cellulose and its derivatives are coded E460 to E466.

### **Use for tobacco products**

The German Tobacco Ordinance (TVO)<sup>125</sup> stipulates that cellulose can be used for artificial wrappers and cigarette paper. Other than this, cellulose is not mentioned in the TVO because the German Provisional Tobacco Act (Vorläufiges Tabakgesetz) stipulates that substances which occur naturally in tobacco may in principle be used as ingredients<sup>126</sup>.

Cellulose is mainly used in cigarette paper and filter wrapper. Cellulose fibres are also used as a binder, filler and processing aid in the production of homogenised tobacco leaf (reconstituted tobacco).

### **Allegations**

The tobacco industry is accused that adding cellulose to cigarettes

- would produce acetaldehyde during combustion, and a possible reaction product that is produced in the body (harmane) could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would increase the toxicity of the tobacco smoke, as cellulose in the cigarette combustion process could lead to the increased formation of aldehydes in the smoke or the toxic combustion product formaldehyde and other toxicologically relevant combustion products, including polycyclic aromatic hydrocarbons (PAH).

### **Arguments**

**Cellulose is not used as a tobacco ingredient to influence the taste or aroma of tobacco products. Cellulose is a raw material for manufacturing paper and therefore a component of the cigarette paper. Cellulose is an essential component for the production of tobacco products such as cigarettes.**

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<sup>125</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>126</sup> Preliminary Tobacco Law version September 9, 1997 (BGBl. I S. 2296), last amended by Artikel 2 Absatz 16 of the law of December 22, 2011 (BGBl. I S. 3044); §20; Absatz (2); 1.

**Many substances in tobacco – including naturally occurring cellulose in the tobacco leaf – contribute to the formation of aldehydes and other toxicologically relevant substances. The use of cellulose in the production of cigarettes does not result in larger quantities of acetaldehyde in the tobacco smoke.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content.

The majority of the compounds found naturally in tobacco, such as carbohydrates (pectins, starches), waxes, fats and nitrogen compounds, which in total account for around 40% of tobacco weight, are considered a source of the formation of aldehydes during the pyrolysis/combustion of tobacco. Cellulose, which makes up 10% of the tobacco leaf, is only one among many other compounds<sup>127</sup>. This is confirmed by toxicological *in vitro* test results, which show that tobacco cellulose also is a significant contributor to the biological activity of tobacco smoke<sup>128</sup>. Nevertheless, despite decades of research, the contribution of individual substances to the overall biological activity of tobacco smoke is not sufficiently clarified.

**Cellulose is a polysaccharide consisting of long chains of glucose molecules. The addition of cellulose to the tobacco of cigarettes does not result in larger quantities of acetaldehyde in the tobacco smoke. Extensive data clearly refutes the two key claims, firstly that the addition of compounds containing sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>129</sup>. The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised quickly in the body and that no mechanism could be found, by which cellulose could contribute to increased dependence<sup>130</sup> or the formation of harmane – which is pharmacologically active in the central nervous system – from acetaldehyde in the human body. Harmane occurs naturally in many foods, including coffee, and also tobacco. The latest research results clearly show that there is no correlation between the amount of harmane in human blood and the quantity and type of products containing harmane that are consumed<sup>131</sup>.

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<sup>127</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

<sup>128</sup> Prefontaine, D., Morin, A., Jumarie, C., and Porter, A.: In vitro bioactivity of combustion products from 12 tobacco constituents; *Food Chem.Toxicol.*; 44 , 2006. 724 - 738.

<sup>129</sup> Seeman, J.I., Doherty, M.C., and Hausmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; *Chem. Res. Toxicol.*; 15, 2002.

<sup>130</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>131</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmane Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; *Journal of Toxicology* 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

**Cellulose is a natural constituent of the tobacco leaf.**

Cellulose forms the basic structure of plants and is the main constituent of plant cell walls. Tobacco blends for cigarettes have a natural cellulose content of 10%<sup>132</sup>.

**DZV members request that all decisions on permitting, restricting or even prohibiting cellulose must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of cellulose increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on cellulose. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>132</sup> Leffingwell, 1999 J.C. Leffingwell, Leaf Chemistry: Basic chemical constituents of tobacco leaf and differences among tobacco types. In: D.L. Davis and M.T. Nielsen, Editors, Tobacco: Production, Chemistry and Technology, Blackwell Science Ltd., London, UK (1999), pp. 268-269.

## **Sugars**

### **Use for tobacco products**

The German Tobacco Ordinance (TVO)<sup>133</sup> stipulates that various types of sugars as defined by the German Sugars Ordinance (Zuckerverordnung), also in caramelised form, may be added to tobacco products.

Sugars are natural constituents of tobacco leaves and may account for up to 30% of the weight of the leaf. Furthermore, various sugars are specifically used in the casing process in the production of traditional American blend cigarettes.

In compliance with the ingredient disclosure requirements<sup>134</sup> companies annually report the amounts of ingredients in use to the competent authorities since 2002. The use levels of components containing sugars, which are added to the tobacco in a traditional American blend cigarette, reach a maximum 4%<sup>135</sup>.

### **Allegations**

The tobacco industry is accused that adding sugars to cigarettes

- would enhance the "attractiveness" of the product and thus facilitates smoking initiation, particularly for young people. Sugars are said to make the tobacco smoke tastes less harsh, and/or sweet;
- would increase the toxicity of the tobacco smoke as sugars in the combustion process in the cigarette could lead to increased formation of formaldehyde in the smoke;
- would produce acetaldehyde during combustion, and a possible reaction product that is produced in the body (harmene) could act together with nicotine on the central nervous system, thus indirectly increasing the dependence potential of cigarettes;
- would reduce the pH value ("acidity") of the smoke. As a result, the amount of "free" nicotine in the smoke would be reduced. This is said to lead to increased consumption and consequently higher exposure of the consumer to toxic smoke components.

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<sup>133</sup> Tobacco Ordinance December 20, 1977 (BGBl. I p. 2831), last amended by the ordinance of July 6, 2010 (BGBl. I p. 851).

<sup>134</sup> The European Parliament and the European Council: 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 of the European Communities L 194 (2001) 26-35. The obligation to report additives was introduced in 2001 and the first report had to be submitted in 2002.

<sup>135</sup> Letter to DG SANCO from the european cigarette association CECCM, December 20, 2011:  
Only a selection of the different sugars is used for a tobacco product. In the reports of 2011 the following amounts per tobacoweight/cigarette of the different sugars have been reported to the Member States: 0,9-3,1% Sucrose; 1,66-3,27% Invertsirup; 0,000023-1,5% Corn sirup; 0-1,06% Glucosesirup; 0-0,07% Molasse; 0-0,6% Honey; 0-0,5% D-Glucose; 0-0,5% High Fructose Corn Sirup; 0-0,2% Maple Sirup; 0,006-0,03% Caramel or 0-0,03% Fructose.

## Arguments

### **The addition of sugars to tobacco does not make the tobacco smoke taste sweet.**

Due to their physico-chemical properties, sugars do not transfer unchanged to the smoke in the burning cigarette while smoking. Instead, they are liable to break down/burn under the effect of heat<sup>136</sup>. As a result, the sweet taste of sugars cannot be transmitted to the tobacco smoke.

### **Any kind of free-market competition is based on the principle of producing a product which is differentiable for an adult consumer. The concept of "attractiveness", however, cannot be used for the scientifically based regulation of tobacco ingredients.**

Various sugars are added to tobacco blends during the manufacturing process to ensure the consistent quality of the product, to achieve a taste that is typical of the brand, and hence make products distinguishable in the market. In the regulatory context, the term "attractiveness" is used in relation to tobacco ingredients without any scientific basis. "Attractiveness" per se is arbitrary and subjective. An EU expert panel (Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR) has concluded that there are no validated methods or reliable data for measuring or assessing the "attractiveness" of ingredients in tobacco products<sup>137</sup>.

### **The addition of sugars to tobacco does not result in larger quantities of acetaldehyde in the tobacco smoke. Extensive data clearly refutes the two key claims, firstly that the addition of sugars results in increased acetaldehyde content of the tobacco smoke, and secondly that acetaldehyde increases the smoker's dependency.**

Tobacco smoke contains various aldehydes, including acetaldehyde. The proportion of acetaldehyde in smoke strongly correlates with a cigarette's condensate and CO content. Data clearly shows that there is no correlation between the acetaldehyde content of tobacco smoke and the quantities of sugars applied to the tobacco<sup>138</sup>.

The main source for the formation of aldehydes in tobacco smoke is the pyrolysis of carbohydrates (including cellulose, starches, pectins), fats and waxes that are already present in the tobacco<sup>139</sup>. In

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<sup>136</sup> Baker, R.R. and Bishop, L.J.: The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions; *J & Anal & Appl & Pyrolysis*; 74, 2005, 145 - 170.

Cahours, X., Verron, T. and Purkis, S: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke; *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>137</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): *Addictiveness and Attractiveness of Tobacco Additives* (ISBN 978-92-79-12788-5), 2010, S.91.

<sup>138</sup> Seeman, J.I., Laffoon, S.W., and Kassman, A.J.: Evaluation of relationships between mainstream smoke acetaldehyde and "tar" and carbon monoxide yields in tobacco smoke and reducing sugars in tobacco blends of U.S. commercial cigarettes; *Inhal.Toxicol*; 15. 2003.

Cahours, X., Verron, T., Purkis, S.: Effect of Sugar Content on Acetaldehyde Yield in Cigarette Smoke. *Beitr. Tabakforsch. Int.* 25 (2012) 381-395.

<sup>139</sup> *Tobacco: production, chemistry and technology*; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 417 ff.

total, the proportion of these compounds in traditional American blend cigarettes amounts to more than 40 percent by weight; this proportion may be higher in Virginia cigarettes, a principal product type in the UK market.

The human body absorbs and metabolises acetaldehyde and other aldehydes very rapidly (in a matter of seconds). Consequently, an increased acetaldehyde concentration cannot be found in the blood of smokers<sup>140</sup>. The experts of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also conclude in their report that acetaldehyde is metabolised very quickly in the body and that no mechanism could be found by which sugars contribute to increased dependence<sup>141</sup> or the formation of the psychoactive substance harmane from acetaldehyde in the human body. Harmane occurs naturally in many foods, including coffee, and tobacco. The latest research results clearly show that there is no correlation between the amount of harmane in human blood and the quantity and type of products containing harmane that are consumed<sup>142</sup>.

**Extensive toxicological studies show that the biological toxic activity of the smoke from cigarettes to which sugars have been added in the quantities seen in the market place, is unchanged compared to cigarettes without the addition of sugars.**

Extensive toxicological studies *in vitro* and *in vivo* show that sugars as tobacco ingredients in the usual quantities do not increase the toxicity of cigarette smoke. As ingredients, sugars change the composition but do not increase the toxicity of cigarette smoke<sup>143</sup>.

The addition of higher amounts (around twice the usual amount) of specific sugars, such as sucrose, to tobacco may result in an increase of the amount of formaldehyde in the tobacco smoke<sup>144</sup>.

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<sup>140</sup> Seeman, J.I., Doherty, M.C. and Haussmann, H.J.: Acetaldehyde in Mainstream Tobacco Smoke: Formation and Occurrence in Smoke and Bioavailability in the Smoker; *Chem.Res.Toxicol.* 15, 2002.

<sup>141</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks): Addictiveness and Attractiveness of Tobacco Additives (ISBN 978-92-79-12788-5), 2010, S.45.

<sup>142</sup> Louis, E.D., Factor-Litvak, P., Gerbin, M., Jiang, W. and Zheng, W.: Blood Harmane Concentrations in 497 Individuals Relative to Coffee, Cigarettes, and Food Consumption on the Morning of Testing; *Journal of Toxicology* 2011, Article ID 628151, 6 pages doi:10.1155/2011/628151.

<sup>143</sup> Gaworski, C. L., Oldham, M. J., Wagner, K. A., Coggins, C. R., and Patskan, G. J. An evaluation of the toxicity of 95 ingredients added individually to experimental cigarettes: approach and methods. *Inhal.Toxicol.*; 22-3-2011.

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Cigarettes with the usual amount of sucrose do not show any increase of the amount of formaldehyde in the tobacco smoke<sup>145</sup>.

**The addition of various sugars to the tobacco of traditional American blend cigarettes does not result in any change in the amount of nicotine available to the smoker in the tobacco smoke.**

The theoretical background for this allegation is the assumption that a change in the "acidity" (pH value) of tobacco smoke will change the proportion of available nicotine in the smoke. There is no correlation between the pH value measured in the smoke and the nicotine content of tobacco smoke<sup>146</sup>.

Tobacco smoke is an aerosol, i.e. a mixture of particulate and gaseous substances. More than 99% of the nicotine in tobacco smoke exists in particulate form<sup>147</sup>. In this particulate form, nicotine is subject to the prevailing pH value in the human body, which via various physiological capabilities keeps its pH value as constant as possible<sup>148</sup>. This mechanism means that the amount of nicotine absorbed by the body is independent of the pH value of the smoke or the protonation state of the nicotine. Furthermore, it is doubtful whether the methods of measuring pH values are applicable in a non-aqueous environment to an aerosol such as tobacco smoke<sup>149</sup>.

**Sugars are natural constituent of tobacco. The addition of sugars to tobacco is necessary for the production of traditional American blend products in order to achieve the characteristic taste of these products and to differentiate the product in a competitive market.**

Sugars are natural constituents of tobacco and may account for up to 30% of the weight of the leaf. While broad-leaved and bright Virginia tobacco varieties consist of up to 30% sugars and small-leaved Oriental tobacco varieties of 10-20% sugars and, therefore, can be used for cigarette production

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<sup>145</sup> Hahn, J. and Schaub, J.: Influence of Tobacco Additives on the Chemical Composition of Mainstream Smoke; Beitr. Tabakforsch. Int. 24 (2010) 100-116.

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<sup>146</sup> Callicutt, C.H., Cox, R.H., Hsu, F., Kinser, R.D., Laffoon, S.W., Lee, P.N., Podraza, K.F., Sanders, E.B., and Seeman, J.I.: The role of ammonia in the transfer of nicotine from tobacco to mainstream smoke; Regul.Toxicol Pharmacol; 46. 2006.

<sup>147</sup> Stevens, N.A., Borgerding, M.F.: GC-AED Studies of Nicotine Fate in a Burning Cigarette; Anal Chem. 1999 Jun 1;71(11):2179-85. PubMed PMID: 21662755.

<sup>148</sup> Benowitz, N.L.: Nicotine pharmacology and addiction; in: Nicotine safety and toxicity, edited by N .L . Benowitz, Oxford University Press, New York, 1998,pp 3-16.

<sup>149</sup> Tobacco: production, chemistry and technology; edited by D. Layton Davis and Mark T. Nielson; 1999; S. 268 ff. and S. 414-415 ff.  
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without further addition of sugars, Burley tobaccos contain hardly any sugars (0-3%)<sup>150</sup>. The sugar compounds in Virginia tobacco contribute significantly to the smoke quality in products made from this variety of tobacco. Virginia tobacco can therefore generally be used without or with only very small quantities of added sugars.

By contrast, in Burley tobacco, which is rich in nitrogen compounds, the sugars are lost during the drying process and are replenished in the casing process. As a result of this production step, Burley tobacco makes an important contribution to the typical taste of traditional American blend products. The amount of sugars added in the production process does not exceed the amount originally present in Burley tobacco after harvesting and before drying (curing) the tobacco<sup>4</sup>. The amounts of components containing sugars, that are added to the tobacco of a traditional American blend cigarette, are typically in the range of 3-4%. Because of their naturally high sugar content, pure Virginia cigarettes may contain a significantly higher proportion of sugars than traditional American blend cigarettes<sup>151</sup>.

**DZV members request that all decisions on permitting, restricting or even prohibiting various sugars as ingredients must be based on sound, objective scientific assessment. This is the only way to ensure reasonable regulation of the use of ingredients in line with public health objectives. This would include, for example, an evaluation of whether or not the addition of sugars increases the risks associated with smoking, and whether or not any restriction or prohibition would reduce the risks associated with smoking.**

Unfortunately, much of the data and findings concerning the influence of various ingredients on smoke chemistry and cigarette smoke toxicity remain unconsidered in this debate. This applies particularly to the debate on sugars. Member companies of the DZV maintain the position that an assessment of ingredients has to give due consideration to all relevant scientific data and findings, including published and peer-reviewed data from tobacco industry scientists.

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<sup>150</sup> Leffingwell, 1999 J.C. Leffingwell, Leaf Chemistry: Basic chemical constituents of tobacco leaf and differences among tobacco types. In: D.L. Davis and M.T. Nielsen, Editors, Tobacco: Production, Chemistry and Technology, Blackwell Science Ltd., London, UK (1999), pp. 265-284.

<sup>151</sup> Phillipotts, D.F., Spincer, D., and Westcott, D.T.: The Effect of the Natural Sugar Content of Tobacco Upon the Acetaldehyde Concentration found in Cigarette Smoke; Beitr. Tabakforsch. Int. 8 (1975) 7–10.  
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