1. ------IND- 2016 0238 D-- EN- ------ 20160602 --- --- PROJET

Draft bill

of the Federal Ministry of Food and Agriculture

Draft Second Ordinance amending the Tobacco Products Ordinance

A. Problem and objective

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC is to be transposed by 20 May 2016. Directive 2014/40/EU is transposed by the Tobacco Products Act of 4 April (Federal Law Gazette I p. f569), as amended by the Act of […], and the Tobacco Products Ordinance enacted on the basis of this Act of 27 April 2016 (Federal Law Gazette I p. 980), last amended by […].

In accordance with Article 7(6), in conjunction with Article 20(3c), of Directive 2014/40/EU, tobacco products, electronic cigarettes and refill containers containing the following additives may not be placed on the market:

– vitamins or other additives that create the impression that a tobacco product, electronic cigarette or refill container has a health benefit or presents reduced health risks;

– caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

– additives having colouring properties for emissions;

– in the case of tobacco products for smoking, electronic cigarettes and refill containers: additives that facilitate inhalation or nicotine uptake;

– additives that have CMR [carcinogenic, mutagenic or reprotoxic] properties in unburnt form.

The additives prohibited in particular must be substantiated by the Member States. Since the regulatory content referred to represents supplementary provisions regarding the stipulations under Directive 2014/40/EU and takes up the stipulations in the directive, this content has to be notified in accordance with Directive (EU) 2015/1535.

B. Solution

The stipulations under Directive 2014/40/EU relating to additives are implemented within the framework of an Amending Order to the Tobacco Products Ordinance. The additives prohibited are listed in Appendices 1 and 2 to the Tobacco Products Ordinance.

Furthermore, the Amending Order makes provision for supplementary regulations relating to the Tobacco Products Ordinance, necessitated as a result of the inclusion of nicotine-free electronic cigarettes and refill containers in the regulation through the Act amending the Tobacco Products Act.

C. Alternatives

None.

D. Budget expenditure without compliance costs

None.

E. Compliance costs

E.1 Compliance costs for citizens

No compliance costs shall be incurred by citizens.

E.2 Compliance costs for businesses

Businesses shall incur a one-off reorganisation cost amounting to EUR 13 000 as a result of this Ordinance. Ongoing compliance costs shall not arise.

The compliance costs associated with the Tobacco Products Ordinance are illustrated therein in detail.

E.3 Administrative compliance costs

No administrative compliance costs shall arise.

F. Additional costs

By means of Annexes 1 and 2, provisions relating to a ban are largely newly introduced with regard to the ingredients of tobacco products, electronic cigarettes and refill containers. In this way, products which do not comply with the stipulations are to be withdrawn from the market.

The result of this may be that the economy may forego profits which hitherto arose through the sale of these products. Lost profits for businesses cannot be estimated since the latter have not made any figures available on demand either.

Draft bill of the Federal Ministry of Food and Agriculture

Second Ordinance amending the Tobacco Products Ordinance[1)]

dated …

The following is decreed on the basis of

§ 5(2) point 3, § 13(2) point 1, § 15(2) and § 23(1) point 1f(aa) of the Tobacco Products Act of 4 April 2016 (Federal Law Gazette I p. 569), by the Federal Ministry of Food and Agriculture, in consultation with the Federal Ministry of Economic Affairs and Energy, and on the basis of

§ 7(2) sentence 2 point 4 of the Tobacco Products Act of 4 April 2016 (Federal Law Gazette I p. 569), as amended by Article 1 of the Act of […], by the Federal Ministry of Food and Agriculture, in consultation with the Federal Ministry of Finance, and on the basis of

§ 6(2) point 1 of the Tobacco Products Act of 4 April 2016 (Federal Law Gazette I p. 569), by the Federal Ministry of Food and Agriculture, in consultation with the Federal Ministry of Economic Affairs and Energy and the Federal Ministry of Health:

Article 1

Amending the Tobacco Products Ordinance

The Tobacco Products Ordinance of 27 April 2016 (Federal Law Gazette I p. 980), last amended by […], is amended as follows:

1. In § 13(4) sentence 1, the words “and water pipe tobacco” are inserted after the words “In the case of roll-your-own tobacco”.

2. § 20(4) is amended as follows:

   a) In sentence 1, the words “in writing” are deleted.

   b) The following sentence 4 is added:

   “Economic operators are obliged to keep the records for three years, starting from the date when the individual distinguishing feature of the tobacco product was made available to the economic operator in accordance with paragraph 1.”

3. In § 24(1) point 3, the words “if the electronic cigarette or the refill container contains nicotine,” are added.

4. In § 26(1) point 5, the words “if the electronic cigarette or the refill container contains nicotine,” are added.

5. § 27 is amended as follows:

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1) Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241 of 17 September 2015, p. 1).

a) Paragraph 1 sentence 2 is amended as follows:

aa) In point 2, the words “if the electronic cigarette or the refill container contains nicotine,” are added.

bb) In point 4, the words “and adolescents” are inserted after the word “children”.

b) Paragraph 2 is worded as follows:

“(2) If the electronic cigarette or the refill container contains nicotine, in addition to the requirements as per paragraph 1, the unit packets and outside packaging must carry the following health warning:

“This product contains nicotine, a substance which is very highly addictive.”

6. The following paragraph 3 is added to § 34:

“(3) Appendix 1 point 4d(aa) shall apply as of 20 May 2020.”

7. Appendix 1 is worded as follows:

“Appendix 1

Prohibited additives in tobacco products

Re § 4

1. Vitamins and the following other additives that create the impression that a tobacco product would offer a health benefit or would carry lower health risks:

a) Amino acids and modified amino acids which are approved for dietary foods pursuant to § 7(1) sentence 1 point 1, in conjunction with Appendix 2 category 3, of the Order on dietetic foodstuffs, as amended, along with S-Adenosyl methionine and L-5-Hydroxytryptophan

b) Carnitine

L-carnitine

L-carnitine hydrochloride

L-carnitine L-tartrate

c) Flavonoids and phospholipids with an antioxidative effect

d) Sodium selenite

2. Caffeine, taurine or the following other additives and stimulant compounds that are associated with energy and vitality:

a) Maltodextrin

b) Components, including processed components, extracts and oils, of the coffee plant and coffee beans

c) Components, including processed components, extracts and oils, of the tea bush *Camellia sinensis* L. *Kuntze*

d) Components, including processed components, extracts and oils, of the guarana plant

e) Components, including processed components, extracts and oils, of the yerba mate

f) Thujone

3. Additives having colouring properties for emissions

4. The following additives in the case of tobacco products for smoking that facilitate inhalation or nicotine uptake:

a) p-menthane-3 substituted and modified compounds, including

p-menthane-3-carboxamide, including p-menthane-3-N-[alkyl]carboxamide

p-menthane-3-ester

p-menthane-3-ether

p-menthane-3-carboxylic acids and their esters

Menthone 1,2-glycerol ketal (CAS No 63187-91-7)

b) p-menthane alcohols and their esters

c) The following compounds:

3,4-dihydro-3-(2-hydroxyphenyl)-6-(3-nitrophenyl)-(1H)-pyrimidine-2-on (CAS No 36945-98-9)

2-isopropyl-N 2,3-trimethylbutyramide (CAS No 51115-67-4)

Isopulegol (CAS No 7786-67-6 or 89-79-2)

1-(di-sec-butyl-phoshine)-heptane

d) The following substances:

aa) Menthol (CAS No 1490-04-6)

(-)-menthol (CAS No 2216-51-5)

(+)-menthol (CAS No 15356-60-2)

bb) Menthone (CAS No 89-80-5)

(-)-menthone (CAS No 14073-97-3)

(+)-menthone (CAS No 3391-87-5)

L-carvone (CAS No 6485-40-1)

Geraniol (CAS No 106-24-1)

Linalool (CAS No 78-70-6)

1,8-cineole (Eucalyptol) (CAS No 470-82-6)

Hydroxycitronellal (CAS No 107-75-5)

e) The following substances derived from plants:

Oils and components which originate from plants of the genera *Mentha*, *Eucalyptos*, *Ocimum*, *Thymus* and *Salvia*

5. The following additives that have CMR properties in unburnt form:

a) Substances which are classified as category 1A, 1B or 2 CMR substances in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [of 16 December 2008] on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 351 of 31 December 2008, p. 1), last amended by Regulation (EU) 2015/491 (OJ L 78 of 24 March 2015, p. 12).

b) The following additional substances:

Birch tar oil (CAS No 8001-88-5 and CAS No 85940-29-0)

Juniper tar oil (CAS No 8013-10-03)

Sassafras oil

Sassafras wood

Sassafras leaves

Sassafras bark

Methyl eugenol (CAS No 93-15-2)

Estragole (CAS No 140-67-0)

Para-hydroxybenzoic acid propyl ester (CAS No 94-13-3)”

8. Appendix 2 is worded as follows:

“Appendix 2

Prohibited ingredients in electronic cigarettes and refill containers

Re § 28

1. Vitamins and the following other additives that create the impression that the consumption of an electronic cigarette or a refill container would have a health benefit or present reduced health risks:

a) Amino acids and modified amino acids which are approved for dietary foods pursuant to § 7(1) sentence 1 point 1, in conjunction with Appendix 2 category 3, of the Order on dietetic foodstuffs, as amended, along with S-Adenosyl methionine and L-5-Hydroxytryptophan

b) Carnitine

L-carnitine

L-carnitine hydrochloride

L-carnitine L-tartrate

c) Flavonoids and phospholipids with an antioxidative effect

d) Sodium selenite

2. Caffeine, taurine or the following other additives and stimulant compounds that are associated with energy and vitality:

a) Maltodextrin

b) Glucose, fructose and galactose

c) Components, including processed components, extracts and oils, of the coffee plant and coffee beans

d) Components, including processed components, extracts and oils, of the tea bush *Camellia sinensis* L. *Kuntze*

e) Components, including processed components, extracts and oils, of the guarana plant

f) Components, including processed components, extracts and oils, of the yerba mate

g) Thujone

3. Additives having colouring properties for emissions

4. The following additives that facilitate inhalation or nicotine uptake:

Menthol (CAS No 1490-04-6)

(-)-menthol (CAS No 2216-51-5)

(+)-menthol (CAS No 15356-60-2)

5. The following additives that have CMR properties in unburnt form:

a) Substances which are classified as category 1A, 1B or 2 CMR substances in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [of 16 December 2008] on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 351 of 31 December 2008, p. 1), last amended by Regulation (EU) 2015/491 (OJ L 78 of 24 March 2015, p. 12).

b) The following additional substances:

Birch tar oil (CAS No 8001-88-5 and CAS No 85940-29-0)

Juniper tar oil (CAS No 8013-10-03)

Sassafras oil

Sassafras wood

Sassafras leaves

Sassafras bark

Methyl eugenol (CAS No 93-15-2)

Estragole (CAS No 140-67-0)

Para-hydroxybenzoic acid propyl ester (CAS No 94-13-3)

6. The following ingredients, excluding nicotine, in the liquid which, when heated or in its unheated form, pose a risk to human health:

b) The following flavourings:

Diacetyl (2,3-butanedione) (CAS No 431-03-8)

2,3-pentanedione (CAS No 600-14-6)

2,3-hexanedione (CAS No 3848-24-6)

2,3-heptandion (CAS No 96-04-8)

Coumarin

c) The following substances derived from plants:

Bitter almond oil

Processed components and extracts of the rootstock of the common polypody

Processed components, extracts and oils which originate from the Pennyroyal plant

Agaric acid”

Article 2

Entry into force

Sentence 2 notwithstanding, this Ordinance shall enter into force on the day following promulgation. Article 1 points 7 and 8 shall enter into force as of 20 May 2016.

Approved by the *Bundesrat*.

Explanatory statement

A. General Part

I. Objective and necessity of the provisions

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC is to be transposed by 20 May 2016. Directive 2014/40/EU is transposed by the Tobacco Products Act of 4 April (Federal Law Gazette I p. f569), as amended by the Act of […], and the Tobacco Products Ordinance enacted on the basis of this Act of 27 April 2016 (Federal Law Gazette I p. 980), last amended by […].

Since the regulatory content referred to represents supplementary provisions regarding the stipulations under Directive 2014/40/EU and takes up the stipulations in the directive, this content has to be notified in accordance with Directive (EU) 2015/1535.

II. Main content of the draft

In accordance with Article 7(6), in conjunction with Article 20(3c), of Directive 2014/40/EU, tobacco products, electronic cigarettes and refill containers containing the following additives may not be placed on the market:

– vitamins or other additives that create the impression that a tobacco product, electronic cigarette or refill container has a health benefit or presents reduced health risks,

– caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality,

– additives having colouring properties for emissions,

– in the case of tobacco products for smoking, electronic cigarettes and refill containers: additives that facilitate inhalation or nicotine uptake,

– additives that have CMR properties in unburnt form.

The additives prohibited in particular must be substantiated by the Member States. They are listed in Appendices 1 and 2 to the Ordinance.

Furthermore, the Amending Order makes provision for supplementary regulations relating to the Tobacco Products Ordinance, necessitated as a result of the inclusion of nicotine-free electronic cigarettes and refill containers in the regulation through the Act amending the Tobacco Products Act.

The attendant health risks posed by nicotine-free electronic cigarettes and refill containers follow from inhaling an aerosol which, regardless of the nicotine, contains substances that are harmful to health. The Federal Institute for Risk Assessment, in its scientific evaluation of 25 February 2015, and the German Cancer Research Centre, in its opinion from 2015, have arrived at these findings. Both the aforementioned institute and centre state that carbonyl compounds, including formaldehyde, acrolein and acetaldehyde, originate when

consuming both electronic cigarettes containing nicotine and those which are nicotine-free. Carbonyl compounds and acetaldehyde are suspected of causing cancer. As of 1 April 2015, formaldehyde is classified as carcinogen category 1B in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 of 31 December 2008, p. 1) (Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 167 of 6 June 2014, p. 36), which means that the carcinogenic effect shall be regarded as probable in the case of people. Acrolein can also cause irritation and inflammation of the exposed mucous membranes and lead to necrosis of the lung tissue when inhaled. Under certain conditions, exposure to formaldehyde and other carbonyl compounds may be similar to that experienced with traditional tobacco cigarettes. There is no threshold value below which a blending of these substances would be quite safe.

III. Alternatives

None.

IV. Compatibility with European Union law and international treaties

Application of the bans on additives arising from Appendix 2 to also include nicotine-free electronic cigarettes and refill containers is compatible with the laws of the European Union. According to Recital 55 of the directive, a Member State should remain free to maintain or introduce national laws [applying to all products placed on its national market] for aspects not regulated by this directive.

V. Legal consequences

1. Legal and administrative simplification

Essentially applying the same regulations to nicotine-free electronic cigarettes and refill containers and those which do contain nicotine represents an administrative simplification for the supervisory authorities in the Federal States.

2. Sustainability aspects

The Ordinance is in keeping with the basic ideas of the Federal [German] Government regarding sustainable development in the context of the sustainability strategy. By means of the Ordinance, avoidable risks for human health are to be reduced. Consideration is thereby given to the indicator “Living Longer and in a healthier way.” The measures laid down in this Ordinance assist in improving the state of health of the population.

3. Budget expenditure without compliance costs

None.

4. Compliance costs

Compliance costs for citizens

No compliance costs shall be incurred by citizens.

Compliance costs for businesses

Owing to the amendment of § 27(1) sentence 2 point 4, the notice to be affixed to the unit packet and outside packaging is to be supplemented by two words. In consultation with the Federal Statistical Office, revision of the existing text is estimated to require one hour's work. The number of label designs is assumed to be 200, meaning one-off reorganisation costs in the region of EUR 13 000 (200 cases x EUR 65.90/hour x 1 hour). Ongoing compliance costs shall not arise.

The compliance costs associated with the Tobacco Products Ordinance are illustrated therein in detail.

Administrative compliance costs

No administrative compliance costs shall arise.

5. Other legal consequences

By means of Appendices 1 and 2, provisions relating to a ban are introduced with regard to the ingredients of tobacco products, electronic cigarettes and refill containers. As a result, products which do not comply with the stipulations are to be withdrawn from the market.

The result of this may be that the economy may forego profits which hitherto arose through the sale of these products. Lost profits for businesses cannot be estimated since the latter have not made any figures available on demand either.

VI. Time limitation; evaluation

A time limitation cannot be imposed on the Ordinance.

B. Specific Part

Re Article 1 (Amending the Tobacco Products Ordinance)

Re point 1

§ 13 of the Tobacco Products Act describes requirements in terms of the general warning and the information messages in the case of cigarettes, roll-your-own tobacco and water pipe tobacco. Since water pipe tobacco is sold in cuboid and cylindrical packets, as regards the cylindrical packets in § 13(4), water pipe tobacco shall be included alongside roll-your-own tobacco.

This is necessary in order to ensure the capacity to act in terms of execution with regard to the assessment of the affixing of the warning and the information messages in the case of cylindrical packets of water pipe tobacco.

The enabling act is § 6(2) point 1 of the Tobacco Products Act.

Re point 2

Re letter a

Letter a contains a clarification of the intention.

The enabling act is § 7(2) sentence 2 point 4 of the Tobacco Products Act.

Re letter b

As regards information to be tracked, such as invoice and order numbers as well as payment receipts from all the purchasers in the distribution chain within the meaning of § 20(1) point 2 of the Tobacco Products Ordinance, it is recommended stipulating retention periods. Especially in the case of special tobacco products, such as water pipe tobacco, to some extent, a high level of market fluctuation is envisaged, involving the setting up and closure of businesses.

The enabling act is § 7(2) sentence 2 point 4 of the Tobacco Products Act.

Re point 3

Clarification is provided of the fact that the provision under § 24(1) point 3 of the Tobacco Products Ordinance shall only apply to nicotine-containing electronic cigarettes and refill containers. § 24(1) transposes Article 20(3) of Directive 2014/40/EU and cites the information which has to be communicated by manufacturers and importers of electronic cigarettes or refill containers. Point 3 concerns information relating to the nicotine dose and uptake and consequently does not apply to nicotine-free electronic cigarettes or refill containers.

The enabling act is § 23(1) point 1f(aa) of the Tobacco Products Act.

Re point 4

Clarification is provided of the fact that the provision under § 26(1) point 5 shall only apply to nicotine-containing electronic cigarettes and refill containers. In transposition of Article 20(4a) of Directive 2014/40/EU, § 26 sets out the requirements which are imposed on the package insert which has to be included in the packet as per § 15(1) point 1 of the Tobacco Products Act. Point 5 concerns the addictive nature and shall only apply to products containing nicotine.

The enabling act is § 15(2) point 1 of the Tobacco Products Act.

Re point 5

Re letter a

§ 27(1) transposes Article 20(4b) and (4c) of Directive 2014/40/EU and sets out the requirements pertaining to the design of unit packets and outside packaging of electronic cigarettes and refill containers.

Point 2 sets out the obligation regarding the indication of nicotine content and nicotine output per dose and does not apply to nicotine-free products.

The amendment of point 4 also assists in adaptation in line with the Act on the protection of children and adolescents against the dangers associated with the consumption of electronic cigarettes and electronic shisha pens of 3 March 2016 (Federal Law Gazette I p. 369).

The enabling act is § 15(2) points 3 and 4 of the Tobacco Products Act.

Re letter b

§ 27(2) transposes Article 20(4b)(iii) of Directive 2014/40/EU and prescribes a warning for nicotine-containing electronic cigarettes and refill containers which relates to the nicotine content. The provision cannot apply to nicotine-free products.

The enabling act is § 15(2) point 2 of the Tobacco Products Act.

Re point 6

Since the additives indicated in Appendix 1 point 4d(aa) are not only regarded as additives that facilitate inhalation or nicotine uptake but, at the same time, are to be classified as characterising flavours within the meaning of Article 7(14) of Directive 2014/40/EU, this provision shall only apply in transposition of Article 7(14) referred to as of 20 May 2020.

Re point 7

Appendix 1 of the Tobacco Products Ordinance is reworded by means of point 7.

Point 1:

Appendix 1 point 1 transposes Article 7(6a) of Directive 2014/40/EU and includes the principle postulated therein whereby, in addition to the vitamins specifically named, additives which are designed to evoke the health-related impressions or associations cited on the part of consumers, or in accordance with the suggestions of the manufacturers, are also prohibited. At the same time, it is irrelevant whether a health benefit or reduced health risk on the basis of scientific criteria is actually inherent in these additives.

Letter a:

Certain amino acids and modified amino acids are approved as additives for dietary foods in the Order on dietetic foodstuffs as per § 7(1) point 1 in Appendix 2 category 3. The human body needs essential amino acids (in specific situations or for certain illnesses or disorders, semi-essential and conditionally essential amino acids) and must absorb these from food. In this respect, amino acids have important physiological functions in the human body and a health benefit is associated with them.

Letter b:

Carnitine, including L-carnitine, L-carnitine hydrochloride and L-carnitine-L-tartrate, are likewise approved under the Order on dietetic foodstuffs as ingredients in foodstuffs intended for particular nutritional uses. Carnitine plays an essential role in the energy metabolism of animal cells and is often recommended as a supplement where the intention is to lose weight so as to achieve improved fatty acid conversion.

Letter c:

Anti-oxidant effects are especially ascribed to flavonoids and phospholipids with an antioxidative effect on account of their cell-protecting function and their properties as radical scavengers.

Letter d:

Selenium is an essential trace element and is frequently obtained through dietary supplements. In addition to oral intake, the inhalation of sodium selenite is also promoted by suppliers of inhalers with a view to improving immune function.

Point 2:

Appendix 1 point 2 transposes Article 7(6b) of Directive 2014/40/EU and includes the principle postulated therein whereby, in addition to caffeine and taurine, other additives and stimulant compounds that are associated with energy and vitality are also prohibited. As is the case under point 1, it is not necessary that these additives or stimulant compounds actually enhance mental alertness or physical performance.

Maltodextrin is a readily available carbohydrate which is frequently used as an energy source in sports nutrition.

Coffee, coffee beans, tea, guarana and mate tea are widely associated with stimulating properties on account of their caffeine content.

Thujone is especially promoted in absinthe on account of its possible euphoric and aphrodisiac effects.

Point 3:

Point 3 transposes Article 7(6c) of Directive 2014/40/EU and includes the principle whereby additives having colouring properties for emissions are prohibited.

Point 4:

Point 4 transposes Article 7(6d) of Directive 2014/40/EU and includes the principle whereby additives that facilitate inhalation or nicotine uptake are prohibited in the case of tobacco products for smoking.

According to letters a to e, certain TRPM8 agonists are prohibited. The scientific assessment carried out by the Federal Institute for Risk Assessment has revealed that activation of the TRPM8 is the key physiological mechanism of action which facilitates inhalation by masking the components of smoke which cause respiratory tract irritation. Known TRPM8 agonists are listed and assigned to certain groups of substances.

Menthol, which is a monocyclic terpene and exists as a component of essential oils in various species of the plant genus *Mentha*, must be particularly emphasised in this regard. The pharmacological effects have been investigated adequately on the basis of a scientific assessment carried out by the Federal Institute for Risk Assessment and include an activation of heat-sensitive receptors, whereby a cooling effect arises in the area of the tongue and oral cavity. Added to this is a local anaesthetic effect. The effects may alleviate the excitations and irritations in the oral cavity and pharynx and, as a result, suppress the natural defence mechanisms associated with the inhalation of tobacco smoke.

Point 5:

Point 5 transposes Article 7(6d) of Directive 2014/40/EU and includes the principle whereby additives that have CMR properties in unburnt form are prohibited.

Letter a:

Under letter a, reference is made to substances which are classified as category 1A, 1B or 2 CMR substances in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008. Category 1A CMR substances are substances where proof has been furnished of their CMR properties in people. Category 1B substances are substances where proof has been furnished of their CMR properties in experiments involving animals. Category 2 substances are substances which are suspected of having CMR properties. All these substances are prohibited from being used as additives for reasons to do with preventative health protection.

Letter b:

Letter b lists other substances having CMR properties.

According to a scientific assessment carried out by the Federal Institute for Risk Assessment, birch tar oil and juniper tar oil have relatively high levels of polycyclical aromatic hydrocarbons (PAH). PAH have been found to be carcinogenic. The high PAH contents arise as a result of the particular production methods of both oils, which differ from other oils.

Sassafras oil, sassafras wood, sassafras leaves and sassafras bark are classified as genotoxic and carcinogenic according to the Federal Institute for Risk Assessment.

The same applies to methyl eugenol and estragole on account of their carcinogenic effects.

As regards para-hydroxybenzoic acid propyl esters (E 215, E 216 and E 217), according to the Federal Institute for Risk Assessment, they exhibit indications of reprotoxic effects.

The enabling act is § 5(2) point 3 of the Tobacco Products Act.

Re point 8

Appendix 2 of the Tobacco Products Ordinance is reworded by means of point 8.

Points 1 to 5 transpose Article 20(3c) of Directive 2014/40/EU, according to which, additives which are prohibited for tobacco products pursuant to Article 7(6) of Directive 2014/40/EU shall also be prohibited in the case of electronic cigarettes and refill containers. At a national level, there has been an extension of this principle inasmuch as the bans shall also apply to nicotine-free electronic cigarettes and refill containers.

Point 1:

Reference is made to the explanation under Appendix 1 point 1.

Point 2:

Reference is made to the explanation under Appendix 1 point 2.

Glucose, fructose and galactose are the most well-known simple sugars, they are rapidly available energy sources, and are therefore associated with energy and vitality.

Point 3:

Reference is made to the explanation under Appendix 1 point 3.

Point 4:

The Federal Institute for Risk Assessment points to a current study which demonstrates that menthol alleviates the irritating sensory effects of liquids which have high (24 mg/ml) nicotine contents (Rosbrook & Green, 2016). This state of affairs suggests that in the case of electronic cigarettes with high nicotine contents, menthol can make getting started with vaping easier. Given the inhibition of nicotine depletion by menthol which has been verified in relation to cigarettes (Benowitz et al., 2004), the opportunity is also envisaged that a similar effect may also arise in the case of electronic cigarettes containing menthol.

Point 5:

Reference is made to the explanation under Appendix 1 point 5.

Point 6:

Point 6 transposes Article 20(3e) whereby, apart from nicotine, only ingredients which do not pose a risk to human health in their heated or non-heated forms may be used.

Letter a:

Different flavourings are listed under letter a. Diacetyl is approved as a flavouring similar to butter for foodstuffs although, according to the Federal Institute for Risk Assessment, it can cause serious inflammation of the respiratory tract during inhalation. According to the Federal Institute for Risk Assessment, this danger likewise exists as regards several structurally similar diketones, in particular 2,3-pentanedione, 2,3-hexanedione and 2,3-heptandion.

In the case of coumarin, according to the Federal Institute for Risk Assessment, the tolerable daily intake value (TDI value) deduced by the European Food Safety Authority (EFSA) of 0.1 mg/kg of body weight is already exceeded as a result of absorption via nourishment or other exposure routes. As a result of the possible use in the liquid of electronic cigarettes or refill containers, an additional exposure route would emerge which increases the health risk in terms of overall exposure.

Letter b:

In the case of bitter almond oil, on the basis of a scientific assessment carried out by the Federal Institute for Risk Assessment, considerable uncertainties exist regarding the possible hydrocyanic acid levels of the oils used. Given the significant hazard potential of hydrocyanic acid, the Federal Institute for Risk Assessment therefore recommends a ban on bitter almond oil.

The rootstock of the common polypody, components and extracts of which contain toxic saponins according to the Federal Institute for Risk Assessment.

Pennyroyals, the components, extracts and oils of which contain a monoterpenoid which, *inter alia*, acts in a hepatotoxic way, as evaluated by the Federal Institute for Risk Assessment.

According to the Federal Institute for Risk Assessment, agaric acid paralyses the smooth muscles in the same way as a toxin.

The enabling act is § 13(2) point 1 of the Tobacco Products Act.

Re Article 2 (Entry into force)

Article 2 regulates the entry into force. The provisions of the Second Amending Order shall enter into force on the day following promulgation. The amendments to Appendices 1 and 2 of the Tobacco Products Ordinance shall enter into force retrospectively on 20 May 2016.

An assurance in need of protection to the extent that, beginning 20 May 2016, only the placement on the market of tobacco products, electronic cigarettes and refill containers which contain the additives listed in the version of the Tobacco Products Ordinance of 4 April 2016 is prohibited, does not exist. Article 2 does not therefore deploy any retroactive effect which is not permitted under constitutional law.

On the one hand, the obligation under EU law concerning the transposition of Article 7(6) of the Tobacco Products Directive, also in conjunction with Article 20(3c) of the same, prevents the emergence of a "situation of trust". The provisions prohibit the placement on the market of tobacco products, electronic cigarettes and refill containers containing the following additives:

- vitamins or other additives that create the impression that a tobacco product, electronic cigarette or refill container has a health benefit or presents reduced health risks,

- caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality,

- additives having colouring properties for emissions,

- in the case of tobacco products for smoking, electronic cigarettes and refill containers: additives that facilitate inhalation or nicotine uptake,

- additives that have carcinogenic, mutagenic or reprotoxic properties in unburnt form.

The Tobacco Products Directive does not allow Member States any leeway in terms of implementing the ban on the placement on the market of tobacco products, electronic cigarettes and refill containers containing additives which come under these categories referred to in Article 7(6) of the aforementioned directive. The bans shall apply as of 20 May 2016.

The Tobacco Products Ordinance in the version of 4 April 2016 only includes the additives specifically named in the directive. In addition, the additives which come under the categories in Article 7(6) of the directive have to be substantiated for legal reasons. With the amendments to Appendices 1 and 2 of the Tobacco Products Ordinance, this is to be effected by means of the Second Amending Order relating to the Tobacco Products Ordinance.

On the other hand, the Second Order amending the Tobacco Products Ordinance was notified on […] in accordance with the provisions of Directive (EU) 2015/1535. On 19 May 2016, it was announced in the Federal Gazette that the Federal Ministry of Food and Agriculture is intending to amend Appendices 1 and 2 of the Tobacco Products Ordinance. Tobacco industry organisations were made aware of this announcement in writing.