

International Regulatory Changes

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TMA Annual Meeting & Conference
May 11, 2017

FCTC Articles 9-10, Product Regulation & Disclosure

Partial Guidelines, adopted at COP4, amended at COP5 & 7

Purpose is to assist Parties in meeting their obligations under Articles 9 & 10

Measures that Parties could introduce to regulate ingredients include

- Prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products
 - “Masking tobacco smoke harshness with flavors contributes to promoting and sustaining tobacco use. Examples of flavoring substances include benzaldehyde, maltol, menthol and vanillin”
- Prohibiting or restricting ingredients that have coloring properties
 - Examples of coloring agents include inks and pigments e.g. titanium dioxide in filter material
- Prohibiting ingredients that may create the impression that they have a health benefit
- Prohibiting ingredients associated with energy and vitality, such as stimulant compounds

FCTC Articles 9-10, Product Regulation & Disclosure

COP7, New Delhi, November 2016

Working Group Report invited COP to review and consider adopting Annexes 1, 2 and 3 proposed for insertion into the existing partial guidelines on Articles 9 and 10:

- **Annex 1: Addictiveness**

Introducing a definition of addictiveness

- **Annex 2: Characteristics Disclosure**

Prohibition or restriction of tobacco products' design features based on attractiveness (slim cigarettes and capsules)

- **Annex 3: Contents Disclosure**

Disclosure of tobacco products contents and emissions based on FCTC and TobLabNet standards

- **Annex 4: Contents Regulation [included for information only]**

Regulation of content to minimize addictiveness (nicotine reduction)

FCTC Articles 9-10, Product Regulation & Disclosure

COP7, New Delhi, November 2016

Outcomes

- Annex 1 was not included in the guidelines. Further work will be undertaken in a step-by-step approach
- Annex 2 was included in the guidelines with amendments:
 - Recommendation is to regulate (not prohibit) and references to slims and capsules have been deleted
- Annex 3 was included with amendments:
 - Parties should consider where it is appropriate specifying references that FCTC and TobLabNet standards could be used
- Annex 4 noted and discussed but not incorporated

FCTC Articles 9-10, Product Regulation & Disclosure

COP8, Geneva, October 2018

Working group mandated to continue its work in elaborating guidelines in a step-by-step process and submit draft partial guidelines or a progress report

Convention Secretariat asked, a.o., to

- Hold a meeting with experts on addictiveness and dependence to study/examine the current and emerging knowledge base, including scientific and empirical evidence, on addictiveness reduction measures and report back to COP8
- Finalize the validation of the analytical chemical methods for aldehydes and volatile organic compounds in cigarette emissions
- Assess the availability of validated analytical methods on the expanded list of toxicants in contents and emissions

EU, Tobacco Products Directive (TPD2)

Product Regulation

Adopted in 2014, transition period until May 20, 2017

- Article 3: Maximum emission levels
10-1-10 TNCO
- Article 4: Measurement methods
ISO standards and possibility to introduce WHO & FCTC standards
Independent verification laboratories
- Article 5: Reporting of ingredients and emissions
Full by brand disclosure to authorities including toxicological information
- Article 6: Priority list of additives
Comprehensive studies required for particular additives where available data suggest the additive may contribute to toxic, addictive or CMR properties, result in a characterizing flavor, or facilitate inhalation or nicotine uptake
- Article 7: Regulation of ingredients
Ban on products with characterizing flavor, ban on vitamins/caffeine/taurine/additives with CMR properties/additives that facilitate inhalation/that have coloring properties
Menthol derogation from characterizing flavor ban until 2020

EU, Tobacco Products Directive (TPD2)

Priority list of additives – based on proposal from SCENIHR

L 131/90

EN

Official Journal of the European Union

20.5.2016

ANNEX

Priority list of additives used in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations

Additive	Chemical formula (if applicable)	CAS number(s) applicable to the substance (not exhaustive)
Carob bean		9000-40-2, 84961-45-5
Cocoa		84649-99-0, 84649-99-3, 95009-22-6, 8002-31-1
Diacetyl	$C_4H_8O_2$	431-03-8
Fentugreek		68990-15-8, 977018-53-3, 84625-40-1
Fig		90028-74-3
Geraniol	$C_{10}H_{18}O$	106-24-1, 8000-46-2
Glycerol	$C_3H_8O_3$	56-81-5
Guaiacol	$C_6H_4(OH)(OCH_3)$	90-05-1
Guar gum		9000-30-0
Liquorice		68916-91-6
Maltol	$C_6H_6O_3$	118-71-8
Menthol	$C_{10}H_{20}O$	2216-51-5, 15356-60-2, 89-78-1, 1490-04-6, 8006-90-4, 68606-97-3, 84696-51-5, 8008-79-5
Propylene glycol	$C_3H_8O_2$	57-55-6
Sorbitol	$C_6H_{14}O_6$	50-70-4
Titanium dioxide	TiO_2	13463-67-7, 1317-70-0

International developments

Canada

- 2009: Federal Bill C-32 banned most ingredients but exempted menthol
- 2015-2017: Bans on menthol introduced in Nova Scotia, Alberta, New Brunswick, Quebec, Ontario, Prince Edward Island and Newfoundland and Labrador
- March 2017: Order Amending the Schedule to the Tobacco Act (Menthol) will ban menthol at Federal level
- Reference to FCTC Partial Guidelines on articles 9-10 to justify regulating contents to reduce attractiveness
- Order will come into force on October 2, 2017

International developments

Singapore

Consultation in Q1, 2016

- Restricting the sale of flavored tobacco products: that have a flavor, i.e. smell or taste other than tobacco. Examples include menthol as well as fruit and candy flavors
- Reference to TPSAC menthol report to justify restrictions
- Recent statements by the Minister of Health regarding other elements of the consultation (MLPA, PP) but no reference to flavors/menthol

International developments

Taiwan

Consultation in Q1, 2017, on the proposed Tobacco Hazards Prevention and Control Act Amendment Bill

- No person shall sell or display tobacco products with floral, fruit, chocolate, mint or any other additives or flavors banned by the public announcement
- Reference to FCTC Partial Guidelines on articles 9-10 to justify ban
- Reference to EU, US and ‘other advanced countries’

In conclusion

Non-binding FCTC partial Guidelines slowly spreading

Purpose is to assist Parties in meeting their obligations under Articles 9 & 10

Measures that Parties could introduce to regulate ingredients include

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- Prohibiting or restricting ingredients that have coloring properties
- Prohibiting ingredients that may create the impression that they have a health benefit
- Prohibiting ingredients associated with energy and vitality, such as stimulant compounds

Absence of consensus and evidence on issues such as palatability, attractiveness and addictiveness

Enterprising
Open
Challenging

First draft list of EU TPD2 priority ingredients

SCENIHR, draft opinion for consultation

Acetanisole

Aliphatic lactons (including 8 members: gamma-Valerolactone, gamma-Hexalactone, gamma-Heptalactone, gamma-Octalactone, gamma-Nonalactone, gamma-Decalactone, gamma-Undecalactone, gamma-Dodecalactone)

Ammonium Compounds

Benzaldehyde

Benzoic acid and sodium benzoate (2 members)

Benzyl alcohol

Caramel colours

Carob bean extract

Cellulose

Cocoa

β -Damascone

Diacetyl

2-Furfural

Geraniol

Glycerol

Guar gum

Guaiacol

Linalool

Liquorice

Maltol

Menthol

Natural extracts (including 4 members : **fenugreek**, rum, plum extract, **fig** extract)

Phenylacetic acid

Piperonal

Propylene glycol

Sorbitol

Sugars

Titanium dioxide

Vanillin

Weak organic acids (including 8 members : potassium sorbate, sorbic acid, citric acid, acetic acid, butyric acid, lactic acid, 2-methyl butyric acid, potassium citrate)