Cigarette Papers
Legal Compliance, USA/Europe

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By Karl Ludwig Thelen
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- Regulation of Whitening and Combustion Control Agents
- Purity Requirements
- Revision of Tobacco Product Directive
- HPHC – FDA
- FCTC - WHO
## Smoking Demographics USA vs. Europe

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>mn</td>
<td>311</td>
<td>499</td>
</tr>
<tr>
<td>Smoking incidence</td>
<td>%</td>
<td>16 %</td>
<td>27 %</td>
</tr>
<tr>
<td>Retail sales cigarettes</td>
<td>bn</td>
<td>320</td>
<td>655</td>
</tr>
<tr>
<td>Production of cigarettes</td>
<td>bn</td>
<td>385</td>
<td>814</td>
</tr>
<tr>
<td>Export of cigarettes</td>
<td>bn</td>
<td>55</td>
<td>574</td>
</tr>
<tr>
<td>Import of cigarettes</td>
<td>bn</td>
<td>8</td>
<td>373</td>
</tr>
<tr>
<td>Growth rate 2009-2014 CAGR</td>
<td>%</td>
<td>-1,3 %</td>
<td>-1,1 %</td>
</tr>
</tbody>
</table>

- Source: US Census Bureau, Eurostat, Euromonitor
The Legal Framework USA vs Europe

“Family Smoking Prevention and Tobacco Control Act”
- Considered by Congress many times over past decade
- New Law effective 6/22/09
- Provisions become effective in phases


- Specific objectives:
  - Harmonize the presentation of warning labels and improve consumer information, especially to vulnerable groups.
  - Improve mechanisms for reporting and analysing tobacco products.
  - Harmonize the regulation regarding the presence of harmful addictive and attractive substances in tobacco products.
  - Regulate market access to tobacco products.
  - Enable speedy adaptation to technical and scientific progress.
Milestones of cigarette regulation

**USA**
- **1964** First surgeon general report
- **1969** Cigarette adds on TV and radio
- **1972** First ETS report
- **1986** Surgeon General Report on ETS
- **1988** Surgeon General Report on nicotine addiction
- **1990** Airline smoking ban (6 h flights)
- **1993** ETS classified as „Group A“ carcinogen
- **1993** Congress: min. 75% american grown tobacco
- **1995** The President: Program to reduce smoking
- **1996** President Clinton: Program for nicotine-free kids
- **1999** Master Settlement was signed ($ 206 bil.)

**European Union**
- **1966** Self-restraint Guidelines VDC
- **1974** Cigarette adds on TV and radio
- **1985** Report on ETS and MAK-list
- **1988** First report on ETS (vs Asbestos)
- **1993** Self-restraint Guidelines reviewed (adds)
- **1998** Right of smoke-free workplace; certain conditions.
- **2002** Master Agreement VDC-BMG: 5 year payment for tobacco prevention
- **2002** EU ban on tobacco adds
- **2003** Framework Convention on Tobacco Control (FCTC) approved
- **2004** FCTC becomes a national law
FDA now has broad authority…

- Over manufacturing, packaging, marketing and sale of tobacco products
- Over changes in products and development, introduction and communication of less harmful products
- Over regulation of tar, nicotine and “other harmful components”
- Over disclosure of ingredient information
- To require manufacturers to disclose research related to “health and dependency effects or safety” of tobacco products
- Can change/add rules going forward “to protect public health”
Cigarette Paper - Components and basic Demands

Raw Materials
- Fibers
- Fillers
- Burning additives
- Production auxiliaries/aids

Basic Demands
- Appearance
- Runability
- Influence on Smoke Yields
- Legal Compliance of the Cigarette

Compliance with Paper Regulation (Purity)
Chapters of Smoking Prevention and Tobacco Control Act

- Section 900. Definitions
- Section 901. FDA Authority over tobacco products
- Section 902. Adulterated Tobacco Products
- Section 903. Misbranded Tobacco Products
- Section 904. Submission of Health Information
- Section 905. Annual Registration
- Section 906. General Provisions Respecting Control of Tobacco Products (including Good Manufacturing Practices)
- Section 907. Tobacco Product Standards (including ban on flavorings in cigarettes)
- Section 908. Notification and Other Remedies (recall authority)
- Section 909. Records and Reports on Tobacco Products (by manufacturers and importers)
Chapters of Smoking Prevention and Tobacco Control Act continues

- Section 910. Application for Review of Certain Tobacco Products
- Section 911. Modified Risk Tobacco Products
- Section 912. Judicial Review
- Section 913. Equal Treatment of Retail Outlets
- Section 914. Jurisdiction of and Coordination with The Federal Trade Commission
- Section 915. Regulation Requirement
- Section 916. Preservation of State and Local Authority
- Section 917. Tobacco Products Scientific Advisory Committee
- Section 918. Drug Products used to Treat Tobacco Dependence
- Section 919. User Fee
- Section 920. Labeling, Record keeping, Records Inspection

- Article 1 – Aim
- Article 2 – Definitions
- Article 3 – Cigarettes: maximum tar, nicotine and carbon monoxide yields
- Article 4 – Measurement methods
- Article 5 – Labelling
- Article 6 – Further product information
- Article 7 – Product descriptions
- Article 8 – Tobacco for oral use
- Article 9 – Adaptations
- Article 10 – Regulatory procedure
Article 11 – Reporting:

- Subsequent reduction of the maximum yields,
- Possible links between these yields,
- Improvements in health warnings, in terms of size, position and wording,
- New scientific and technical information regarding labelling and the printing on cigarette packets of photographs or other illustrations to depict and explain the health consequences of smoking,
- Methodologies for more realistically assessing and regulating toxic exposure and harm,
- Evaluation of the addictive effects of those ingredients which encourage addiction,
- Evaluation of tobacco products which may have the potential to reduce harm,
- Development of standardized testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide,
- Toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use,
- Development of standards concerning products other than cigarettes, in particular rolling tobacco
Art. 12 Further Product Information – Ingredients Reporting

- Common Reporting Format for Ingredients to Regulators & the General Public

- List of all ingredients present in the tobacco product with exact quantities, by brand and type of product

- Category for Cigarettes
  - Tobacco (burnt)
  - Cigarette Paper (burnt)
  - Side-seam Adhesive & Inks used on Cigarette Paper (burnt)
  - Filtration Material, Filter Over-wrap, Filter Adhesive (unburnt)
  - Tipping Paper & Tipping Paper Inks (unburnt)

- Ingredient Information

- Function of the Ingredient
List of all Ingredients present in the Tobacco Product with exact Quantities, by Brand and Type of Product

<table>
<thead>
<tr>
<th>Column number</th>
<th>Column title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Name of Manufacturer or Importer</td>
</tr>
<tr>
<td>2</td>
<td>Country</td>
</tr>
<tr>
<td>3</td>
<td>Year</td>
</tr>
<tr>
<td>4</td>
<td>Product type</td>
</tr>
<tr>
<td>5</td>
<td>Brand name</td>
</tr>
<tr>
<td>6</td>
<td>Brand Features</td>
</tr>
<tr>
<td>7</td>
<td>Tar yield</td>
</tr>
<tr>
<td>8</td>
<td>Nicotine yield</td>
</tr>
<tr>
<td>9</td>
<td>Carbon monoxide yield</td>
</tr>
<tr>
<td>10</td>
<td>Product unit weight</td>
</tr>
<tr>
<td>11</td>
<td>Tobacco weight</td>
</tr>
<tr>
<td>12</td>
<td>Category</td>
</tr>
<tr>
<td>13</td>
<td>Ingredient name</td>
</tr>
<tr>
<td>14</td>
<td>Ingredient quantity</td>
</tr>
<tr>
<td>15</td>
<td>Ingredient function</td>
</tr>
</tbody>
</table>
## Function of Tobacco Ingredients and Non Tobacco Ingredients (NTIs) in Tobacco Products

<table>
<thead>
<tr>
<th>Function code</th>
<th>Function name</th>
<th>Function code</th>
<th>Function name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Addictiveness enhancer</td>
<td>12</td>
<td>Humectant</td>
</tr>
<tr>
<td>2</td>
<td>Adhesive</td>
<td>13</td>
<td>Plasticiser</td>
</tr>
<tr>
<td>3</td>
<td>Binder</td>
<td>14</td>
<td>Preservative</td>
</tr>
<tr>
<td>4</td>
<td>Carrier</td>
<td>15</td>
<td>Processing aid</td>
</tr>
<tr>
<td>5</td>
<td>Color</td>
<td>16</td>
<td>Solvent</td>
</tr>
<tr>
<td>6</td>
<td>Combustion modifier</td>
<td>17</td>
<td>Sizing agent</td>
</tr>
<tr>
<td>7</td>
<td>Fibre</td>
<td>18</td>
<td>Smoke enhancer</td>
</tr>
<tr>
<td>8</td>
<td>Filler</td>
<td>19</td>
<td>Smoke colour modifier</td>
</tr>
<tr>
<td>9</td>
<td>Filter component</td>
<td>20</td>
<td>Smoke odour modifier</td>
</tr>
<tr>
<td>10</td>
<td>Filtration material</td>
<td>21</td>
<td>Casings</td>
</tr>
<tr>
<td>11</td>
<td>Flavour</td>
<td>22</td>
<td>Other</td>
</tr>
</tbody>
</table>
Ingredient Toxicological Data - Extract

- Name, CAS, FEMA, CoE Numbers, unburnt
- Name, CAS, FEMA, CoE Numbers, burnt
  - Pyrolysis, Smoke Composition
  - In Vitro Toxicological Studies
  - Inhalation Studies
  - Carcinogenetic Studies
  - Cardiovascular Toxicity
  - Addictive Properties

- Reporting Format

<table>
<thead>
<tr>
<th>Available toxicological data for ingredient</th>
<th>Burnt ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of tobacco ingredient</td>
<td></td>
</tr>
<tr>
<td>Unburnt ingredient</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>GROUP</td>
<td>COMPONENT</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
</tr>
<tr>
<td>FIBRES</td>
<td>pulp</td>
</tr>
<tr>
<td>FILLERS</td>
<td>calcium carbonate</td>
</tr>
<tr>
<td>ADDITIVES</td>
<td>trisodium citrate</td>
</tr>
<tr>
<td></td>
<td>tripotassium citrate</td>
</tr>
<tr>
<td>CMC</td>
<td>cellulose, carboxymethyl ether, sodium salt, EC No.: E 466</td>
</tr>
<tr>
<td>guar</td>
<td>guar gum (natural galactomannan)</td>
</tr>
<tr>
<td></td>
<td>water</td>
</tr>
<tr>
<td>PROCESSING AIDS</td>
<td>retention aid, biocides</td>
</tr>
</tbody>
</table>
Remarks:
Material percentages may vary slightly due to process control requirements.
All above listed components are being added during the paper making process.
Intended Usage: Cigarette Paper
Function names are in compliance with the list A of the European Commission (SANCO): Reporting on tobacco product ingredients - Practical guide, issued at May 31, 2007, Brussels.
The paper complies with the German Tobacco Ordinance (TVO) dBGBI 1977 I, p. 2831 in its version dBGBI 2008 I, p. 1295.
The paper complies with the „List of permitted Additives to Tobacco Products in the United Kingdom“, published by the Department of Health, London, October 2003.
Process aids comply with the recommendation XXXVI „paper and board for food contact“ issued by BfR, Germany, status July 1, 2007.
We reserve the right to replace identical products (same CAS number) from different sources without notifying the customer.
Regulation Concerning Tobacco and Tobacco Products (Tobacco Regulation)

- Whitening and combustion control agents
  - Aluminium hydroxide
  - Aluminium sulfate
  - Aluminium oxide
  - Magnesium oxide
  - Titanium dioxide
  - Sodium, potassium, calcium and magnesium compounds of carbonic acid, formic acid, acetic acid, malic acid, citric acid, tartaric acid and nitric acid.
Purity requirements

**E 331 (iii) TRISODIUM CITRATE**

**Synonyms**
- Trisodium citrate
- Tribasic sodium citrate

**Definition**

*Chemical name*
- Trisodium citrate
- Trisodium salt of 2-hydroxy-1,2,3-propanetricarboxylic acid
- Trisodium salt of citric acid, in anhydrous, dihydrate or pentahydrate form

**Einecs**

*Chemical formula*
- Anhydrous: $\text{C}_6\text{H}_5\text{O}_7\text{Na}_3$
- Hydrated: $\text{C}_6\text{H}_5\text{O}_7\text{Na}_3\cdot n\text{H}_2\text{O} \ (n = 2 \ or \ 5)$

**Molecular weight**
- 258.07 (anhydrous)

**Assay**
- Not less than 99% on the anhydrous basis

**Description**
- Crystalline white powder or colourless crystals

**Identification**
- A. Positive tests for citrate and for sodium
## Purity Requirements cont.

<table>
<thead>
<tr>
<th>Purity</th>
<th>Determined by drying at 180 °C for four hours:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td></td>
</tr>
<tr>
<td>Oxalates</td>
<td>Not more than 100 mg/kg expressed as oxalic acid, after drying</td>
</tr>
<tr>
<td>pH of a 5 % aqueous solution</td>
<td>Between 7.5 and 9.0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>Not more than 5 mg/kg</td>
</tr>
</tbody>
</table>
Revision of Tobacco Product Directive by DG Sanco 25.03.2011
Adoption expected by End of 2011

Specific objectives:
- Harmonize the presentation of warning labels and improve consumer information, especially to vulnerable groups.
- Improve mechanisms for reporting and analyzing tobacco products.
- Harmonize the regulation regarding the presence of harmful addictive and attractive substances in tobacco products.
- Regulate market access to tobacco products.
- Enable speedy adaptation to technical and scientific progress.
Options

- Changes to the Labelling Requirements:
  - Replacing quantitative information on tar, nicotine and carbon monoxide (TNCO) on cigarette packages by the qualitative information on harmful substances and information on cessation services.
  - Making pictorial warnings compulsory.
  - Introducing enlarged warnings.
  - Introducing warnings on both sides of the package.
  - Introducing standardized packaging.

- Regulating the Ingredients of Tobacco Products:
  - Introducing common list of ingredients with tackling toxicity, carcinogenicity, mutagenicity, attractiveness and addictiveness.
  - Setting limits for other yields and also for other tobacco products.
  - Further decreasing maximum limits for TNCO.
Initial Assessment of Impacts

- Public health impacts:
  - All the changes are expected to affect positively the health of citizens including life expectancy, mortality and morbidity.
  - Envisaged changes are expected to work towards better cessation information, smoking prevention and less consumption.
## Harmful Chemicals

<table>
<thead>
<tr>
<th>Chemical</th>
<th>H/PH Inhaled from Smoke</th>
<th>H/PH Absorbed or Consumed from Tobacco Products</th>
<th>Analytic Method Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetamide</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Acetaldehyde</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrolein</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrylamide</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrylonitrile</td>
<td>YES</td>
<td></td>
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<tr>
<td>Aflatoxin B-1</td>
<td>YES</td>
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</tr>
<tr>
<td>4-Aminobiphenyl</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1-Aminoanthalene</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2-Aminoanthalene</td>
<td>YES</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Ammonia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ammonium Salts</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anatabine</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beryllium</td>
<td>DEFER</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>1,3-Butadiene</td>
<td>DEFER</td>
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</tr>
<tr>
<td>Butyraldehyde</td>
<td>DEFER</td>
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</tr>
<tr>
<td>Cadmium</td>
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</tr>
<tr>
<td>Caffeic acid</td>
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<tr>
<td>Carbon monoxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobalt</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Catechol</td>
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<tr>
<td>Chlorinated dic</td>
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<td>Chromium</td>
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<td>Chrysene</td>
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<td>Cresols</td>
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<td>Crotonalde</td>
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<tr>
<td>Dibenz(a)</td>
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</tr>
<tr>
<td>Dibenz(a)</td>
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<tr>
<td>Dibenz(e)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dibenzo(a,c)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Dibenzo[a,e]pyrene</td>
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</tr>
<tr>
<td>Dibenzo[a,h]pyrene</td>
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<tr>
<td>Dibenzo[a,i]pyrene</td>
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<tr>
<td>Dibenzo[a,l]pyrene</td>
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</table>
The Global Tobacco Industry - WHO

WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

Conference of the Parties to the WHO Framework Convention on Tobacco Control
Working Group on Articles 9 and 10 of the WHO FCTC
FCTC/COP/4/WG/9&10, 15 May 2010
Draft guidelines for the implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control
The Global Tobacco Industry - WHO

- CONSIDERATIONS IN THE DEVELOPMENT OF THE GUIDELINES
  - Already existing regulation
- PURPOSE, OBJECTIVES AND USE OF TERMS
  - Develop effective Tobacco Product Regulation
  - Assist in Strengthening Tobacco-control Policies through Regulation
  - Testing and Measuring of the Contents and Emissions of Tobacco Products
  - Reducing Attractiveness of Tobacco Products
  - Reducing overall Toxicity of Tobacco Products
  - No Use of Ingredients enhancing Attractiveness and Addictiveness
  - Disclosure to Governmental Authorities
  - Analysis of Tobacco Products Contents and Emissions
  - Monitoring of Market Trends
  - Assessment of Tobacco Industry Claims, Restrictions and Limitations
On a Global Scale the Future of Tobacco Regulation is still unpredictable.

Many Thanks for your Attention

This Information cannot substitute individual legal advice