TOBACCO ADDITIVES - ON THE WAY TO IMPLEMENTATION OF TPD

Dr. Urmila Nair
DKFZ alumna, fmr. senior scientist
German Cancer Research Center,
Heidelberg, Germany
Contact: u.nair.gcrc@gmail.com
The manufacture, presentation and sale of tobacco and related products is regulated by the TPD (revised 2014).

Revised TPD entry into force: May 2014

Member States must transpose the revised TPD (TPD 2014/40/EU) into domestic law by 20 May 2016

OVERVIEW

Implementation status of revised TPD in context of regulation of Tobacco Additives

- Revised reporting format for ingredients and emissions under Article 5
- Priority list of additives and enhanced reporting obligations under Article 6
- Regulation of ingredients under Article 7
Article 5(5) – Type of EC measure-Implementing act
Revised reporting format for ingredients and emissions
Target date-Adoption/publication: Q4 2015

Milestones;
- External contract is currently being finalized
  Stakeholder involvement started 08/2014*
- Member States/Expert Group consultations
- Adoption by the Commission
- Development of the IT tools

‘characterising flavour’ means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product; (TPD 2014/40/EU)
Prohibition of the following:
1) TP (tobacco products) with a characterising flavour.
2) TP containing the following additives
   a) vitamins/additives that create the impression TP has a health benefit or presents reduced health risks;
   b) caffeine or taurine or stimulant compounds associated with energy and vitality;
   c) additives having colouring properties for emissions;
   d) for TP for smoking, additives that facilitate inhalation or nicotine uptake; and
   e) additives that have CMR properties in unburnt form.

Article 7 of Directive 2014/40/EU:
Regulation of ingredients:
Prohibition of the following:

3) TP containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the TP concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine.

4) TP containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a TP at the stage of consumption to a significant or measurable degree.

The provisions outlined above shall apply in the first stage to cigarettes and roll-your-own tobacco. The exemption for other product categories may be removed under certain conditions.
Article 7(3) & (4) - Type of EC measure - Implementing act
Uniform rules for the procedures for determining characterizing flavours + Procedures for the operation and establishment for the independent advisory panel
Target date - Adoption/publication: Q1 2016

Milestones;

- External contract is currently being finalised
- Stakeholder involvement started 12/2014
- Member States/Expert Group consultations
- Adoption by the Commission
Article 6 Priority list of additives and enhanced reporting obligations

1. Priority list to contain additives: for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the following properties:

a) contributes to the toxicity or addictiveness of the products concerned / increases the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;
b) results in a characterising flavour;
c) facilitates inhalation or nicotine uptake; or
d) leads to the formation of substances that have CMR properties / increases the CMR properties in any of the products concerned to a significant or measurable degree; &

2. which are amongst the most commonly used additives by weight or number according to the reporting of ingredients
EC has to develop & update a **priority list** of at least 15 additives contained in cigarettes and RYO tobacco by May 2016.
EC sought scientific opinion from Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to assist the Commission

(1) in identifying the additives that should be put on the priority list
(2) to advise the Commission on the type and criteria for comprehensive studies that should be requested from manufacturers to assess the relevance of the individual additives, considering also the knowledge gaps identified.
Opinion 1

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Preliminary Opinion on Additives used in tobacco products, published 15 July 2015;

Current status; Public consultation completed

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf
Aims to assist the Commission in identifying the additives for the priority list, as foreseen in the TPD, because of their properties that contribute to a product’s

- toxicity or addictiveness,
- result in a characterising flavour,
- facilitate inhalation or nicotine uptake,
- and/or lead to the formation of substances that have carcinogenic, mutagenic properties or that are toxic for reproduction
OPINION 1: PRIORITY ADDITIVES: SELECTION

- Lists from several MS considered, most comprehensive Netherland list 1260 additives taken as typical
- Additives ranked according to the frequency of detection in different brands and highest amount used in cigarettes
- Initial scan was carried out (top 100), considering the categories above (see also Article 6(2 a-d) in the TPD).
- Literature search for data on general characteristics of the compounds, toxicity data (including CMR properties), information about characterising flavour (potentially increasing contributing to attractiveness), inhalation facilitation or increase in nicotine uptake (potentially contributing to addictiveness), data on pyrolysis products and their toxicity.

- Data sheet was prepared for each chemical containing the most relevant, information and criteria for inclusion into the priority list.
Opinion 1: List of priority chemicals*

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>Additional Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-furfural</td>
<td>Sugars and related compounds (caramel colours)</td>
</tr>
<tr>
<td>Geraniol</td>
<td>Natural extracts (fenugreek, rum, plum extract, fig extract, carob bean extracts, guar gum)</td>
</tr>
<tr>
<td>Diacetyl</td>
<td>Cellulose</td>
</tr>
<tr>
<td>Maltol</td>
<td>β-Damascone</td>
</tr>
<tr>
<td>Guaiacol</td>
<td>Vanillin</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Aliphatic lactones (8)</td>
</tr>
<tr>
<td>Benzaldehyde/benzylalcohol/benzoic acid/sodium benzoate</td>
<td>Humectants (Propyleneglycol, Sorbitol, glycerol)</td>
</tr>
<tr>
<td>Cocoa</td>
<td>Ammonium compounds</td>
</tr>
<tr>
<td>Liquorice</td>
<td>Weak organic acids (8)</td>
</tr>
<tr>
<td>Linalool</td>
<td>Acetanisole</td>
</tr>
<tr>
<td>Menthol</td>
<td></td>
</tr>
<tr>
<td>Phenilaceticacid</td>
<td></td>
</tr>
<tr>
<td>Piperonal</td>
<td></td>
</tr>
</tbody>
</table>

* SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Additives used in tobacco products, 15 July 2015; [http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf)
Priority list: enhanced reporting obligations

- Comprehensive studies which shall examine for each additive whether it has any of the properties 1 a) to d) specified earlier

- Studies shall take into account the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned.

- The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned.
Opinion 2:

- Type and criteria for comprehensive studies to assess the relevance of the individual additives, considering the knowledge gaps identified and the interaction of the additive with other additives/ingredients.
- Most suitable methodologies to be used (including a structure of the reports that can be peer reviewed).

To be continued……
Article 6(1) – Type of EC measure-Implementing act

Priority list of additives

Target date-Adoption/publication: Q1 2016

Milestones;

- SCENIHR consultation started 6/2014
  - Public consultation concluded in Q3 2015
  - Final opinion foreseen in Q4 2015

- External contract: started 04/2015. Contract: DIRECTii

- Member State/Expert Group consultations

- Adoption by the Commission
THANK YOU...

Contact: Dr. Urmila Nair
u.nair.gcrc@gmail.com