Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Request for a scientific opinion:

Priority List of Additives used in Tobacco Products

1. Background

The new Tobacco Products Directive 2014/40/EU strengthens the rules regarding the reporting and composition of tobacco products. In addition to tightening the obligations of manufacturers to report on ingredients[1] contained in tobacco products the Directive regulates permissible additives (or levels thereof) in order to improve the functioning of the internal market whilst guaranteeing a high level of public health.

A) Article 7 of Directive 2014/40/EU foresees in particular the prohibition of the following:

1) tobacco products with a characterising flavour. (Art 7(1))
2) tobacco products containing the following additives[2] (Art 7(6)):
   a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
   b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
   c) additives having colouring properties for emissions;
   d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and
   e) additives that have CMR[3] properties in unburnt form.
3) tobacco products 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 tobacco products concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine. (Art 7(7))
4) tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measureable degree. (Art 7(9))

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.

B) Moreover, in line with Article 6 the Commission has to develop and update a **priority list of at least 15 additives** contained in cigarettes and roll your own tobacco by May 2016. This list shall contain additives

1) 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[4];

[1] 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives (TPD 2014/40/EU)

[2] 'additive' means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging (TPD 2014/40/EU)

[3] CMR - carcinogenic, mutagenic or toxic for reproduction

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; and

2) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients.

For these priority additives enhanced reporting obligations will apply in the form of comprehensive studies which shall examine for each additive whether it has any of the properties 1 a) to d) specified above. Those 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. The results of these studies shall assist Member States and the Commission in their enforcement efforts regarding Art. 7.

The SCENIHR has released a scientific opinion on the attractiveness and addictiveness of additives in 2010.[5] In light of the time that has passed since that opinion and the need to address the current regulatory requirements the SCENIHR is asked to address the questions outlined in the Terms of Reference below.

2. Terms of reference

The main purpose of the scientific opinion sought is to assist the Commission in identifying the additives that should be put on the priority list. The scientific opinion can, however, also provide useful input for Member States and the Commission in their broader regulatory/enforcement activities (e.g. setting thresholds/banning of additive), in particular in areas where the knowledge base may currently still be limited. In particular, the Committee is asked the following:

Opinion I

1. Based on scientific evidence (including a review of relevant scientific data) and other relevant information currently available (initial indications, regulation in other jurisdictions), the Committee is asked to identify - for each category separately - those additives that fall/are suspected to fall within the scope of the following categories:

a. Contribution 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. Resulting in a characterising flavour;
c. Facilitating inhalation or nicotine uptake;
d. Leading to the formation of substances that have CMR properties / increasing the CMR properties in any of the products concerned (cigarettes/RYO) to a significant or measurable degree;[6]

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[4] '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)

[5] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031.pdf

[6] If an additive is included in Annex VI of Regulation (EC) No 1272/2008, its CMR-classification should be provided and considered as appropriate. Additives that have CMR properties in unburnt form should be identified/listed, but do not require a comprehensive description.

The assessment should include for each of the additives identified a comprehensive description of the type of information supporting its identification as well as a description and quantification of the strength of the observed characteristic and the strength of the available evidence supporting this finding.[7] If the Committee identifies more than 20 additives for a category, the Committee is entitled to prioritise in the light of the criteria set out in this section. In this case the description is limited to the top 20 additives per category, whilst the other additives can be listed without description.

The Committee is asked to consider in its assessment also the interaction with other ingredients contained in the products concerned and the emissions resulting from the combustion process involving the additive concerned as well as the intended use of the products. Relevant knowledge gaps should be identified.

As far as relevant information is available, the Scientific Committee is asked to identify within its assessment the most commonly used additives by weight or number. If additives belong to a single group of substances with identical or very similar properties, both the group of substances and the list of substances falling into that group shall be presented and the most relevant substance(s) within that group identified.

When examining the composition of tobacco products and the use of individual substances, the Scientific Committee is invited to consult the data on additives reported by tobacco industry under the Tobacco Products Directive 2001/37/EC, but may also consider additional data sources. Furthermore, the Committee is invited to consider during their assessment the lists of additives permitted/prohibited for use in tobacco products as implemented by certain Member States.

2. Based on its assessment in point 1, the Committee is asked to establish a list of minimum 20 and maximum 30 additives that are suitable/recommended to be added to the priority list of additives in line with Article 6 of TPD 2014/40/EU. When establishing the list the Committee shall consider the public health risks associated with the additives (actual or suspected), strength of the available evidence and to the extent possible the frequency of use of the additives in tobacco products. The Committee should indicate as far as possible rankings of additives in light of the above and provide an explanation for its ranking.[8]

Opinion II

3. Furthermore, the Committee is asked 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 inter alia the knowledge gaps identified in point 1 above and the interaction of the additive with other additives/ingredients. Advice is also sought on the most suitable methodologies to be used (including a structure of the reports that can be peer reviewed).

3. Deadline

Opinion I: October 2015
Opinion II: June 2016 (preliminary Opinion)

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[7] Registrations/assessments of relevant substances under Regulation (EC) No 1907/2006 should be provided and considered as appropriate.

[8] Substances belonging to the same group of identical/very similar substances should be considered jointly.