

#### PMI PRODUCT ASSESSMENT AND COMPLIANCE

Department of Health Room 523 Wellington House 133-155 Waterloo Rd. London SE1 8UG United Kingdom

Neuchâtel, 20 September 2012

Re: 2012 Ingredients Reports

The enclosed Ingredients Reports are submitted to the Department of Health pursuant to the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 and Directive 2001/37/EC,<sup>1</sup> and conform to the templates for Table 2 and Table 3 set out in the European Commission's Common Reporting Formats.<sup>2</sup>

As required by the Commission's Guide, we are also submitting the full toxicological data obtained during the reporting year (i.e. any data listed as a "2" in Table 2). This is contained on the enclosed DVD entitled "United Kingdom Toxicological Data 2012."

These Ingredients Reports that include Philip Morris International's products sold in the United Kingdom (both in the domestic and duty free markets) were prepared by Philip Morris Products S.A., Neuchatel, Switzerland, for Philip Morris Limited UK. Philip

<sup>&</sup>lt;sup>1</sup> Article 6, Directive 2001/37/EC of June 5, 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194/26 of 18.7.2001)

<sup>&</sup>lt;sup>2</sup> As issued by the European Commission on 31 May 2007, see http://ec.europa.eu/health/ph\_determinants/life\_style/Tobacco/Documents/practical\_guidance\_en.pdf

<sup>&</sup>lt;sup>3</sup> For your convenience, we have included on the DVD all of the toxicological data available to us for each of the ingredients we use in our products in the United Kingdom

Morris Products S.A. is responsible for the scientific assessment of Philip Morris International's products sold worldwide.

We also intend to provide you with Table 1 of the European Commission's Common Reporting Formats which contains trade secret information. We wish to deliver this Report to you in person to enable us to explain how to access it and in order to receive an acknowledgement of receipt of this sensitive information.

We would appreciate acknowledgement of receipt of this year's report. I Again, to reassure you, the acknowledgment would be brief and concise, and we ask all representatives of Member States provide one upon receipt of this information to acknowledge it formally and properly. In addition, Brett Cooper, our Corporate Affairs representative in the UK would appreciate the opportunity to discuss this report with you and your team. We fully understand that any such meeting or discussions would be completely transparent and in the spirit of the Framework Convention on Tobacco Control (FCTC). Hence, we would be guided by you as to how best to arrange such a discussion.

## Information to Be Made Public

In accordance with Article 6 (2) of Directive 2001/37/EC, any information on ingredients to be made available to the public must exclude trade secrets. For the purposes of making any of our ingredient information available to the public, the Department of Health may use the document entitled Report for the General Public, which is also included on the enclosed CD.

We kindly request that you notify us in advance, and give us the opportunity to comment, should you wish to publish or distribute our study reports contained in the DVD entitled "United Kingdom Toxicological Data 2012".

# Sharing of the Information with the European Commission

Article 6(4) of Directive 2001/37/EC requires Member States to communicate to the European Commission all data and information submitted by manufacturers. To facilitate this process we are enclosing two duplicate CDs containing Tables 2 and 3 and two duplicate DVDs containing the toxicological data.

The undersigned declare on behalf of Philip Morris Products S.A. that the data contained in the enclosed Ingredients Reports is being submitted truthfully.

Yours sincerely.

Chief Scientist Operations

Difector Product Assessment and Compliance



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This DVD contains toxicological data in support of the ingredients report submitted by Philip Morris International. We kindly request you to notify us in advance and give us the opportunity to comment should you wish to publish our study reports contained on this DVD which we did not make public or if you intend to pass them on to other stakeholders.

Start the navigation by clicking on Table 2. Stronggsham and the



Note:

The supported configuration on which this has been tested includes Microsoft Excel, Word 2003 (SP2) and Adobe Acrobat Reader V 7.0



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### Information for the European Commission

Article 6(4) of Directive 2001/37/EC requires Member States to communicate to the European Commission all data and information submitted by manufacturers. To facilitate this process we are enclosing this duplicate CD (coded to allow access to Table 1 by yourself and by the relevant official at the European Commission¹) as well as a duplicate copy of the DVD containing toxicological data.



<sup>&</sup>lt;sup>1</sup> The relevant official at the European Commission is: Dr. Matus Ferech.