APPENDIX A3.2.2-4

EXECUTIVE SUMMARY OF THE PLATFORM 1 BLEND MAINTENANCE STUDY REPORT

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1. INTRODUCTION

The development of Modified Risk Tobacco Products (MRTPs) with the potential to reduce individual risk and population harm is PMI R&D's priority since many years. A key component of this work is to develop products that are eliminating combustion while providing a satisfying consumer experience by heating the tobacco to temperatures below 450° C, rather than burning it.

For the development of PMI's MRTPs which use distillation as their main operating principle, a specific tobacco-based smoking material has been developed – the tobacco substrate. The manufacturing process of the tobacco substrate is based on cast leaf tobacco reconstitution process principles.

Since tobacco is an agricultural product, it varies considerably with a range of drivers of variability including the tobacco type, geographical source, crop year, leaf position on the plant, type of soil, and curing method. The three major types of tobacco are defined by where and how they are grown, and the curing method:

- Virginia flue-cured (FC) tobacco is cured for less than a week under controlled variations of temperature and humidity; throughout this process, starch conversion to sugars occurs.
- Burley tobacco (BU) is fertilized more heavily than flue-cured, and is typically air-cured for 30-40 days without heat; throughout this process, the tobacco loses essentially all its sugar content.
- Oriental tobacco (OR) is grown in Mediterranean-style climatic conditions, with fertilization applied only to promote early growth; oriental tobacco is sun-cured.

In addition to the three major tobacco types, other tobacco types are produced for specific tobacco products. For example:

- In Indonesia air-cured or sun-cured Kasturi (AC/SC-ID-KS) is produced, mainly for Kretek cigarettes.

(b) (4)

as illustrated in Figure 1.

(b) (4)

, according to a Blend Maintenance Strategy, as illustrated in Figure 2: as (b) (4)

(b) (4)

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Figure 1: (b) (4)



Figure 2: Graphical Overview of the Crop Mixing Principle for a Specific Blend Component (Ci)

Note: YYYY + n refer to different Lot Sets used e.g. in different production years.

The present study was designed to assess the impact of variations in the chemical constituents of the raw tobaccos on the performance of the final product, in order to define a Blend Maintenance Strategy for THS 2.2.

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2. OBJECTIVES

The primary objective of the Blend Maintenance Study was to define the blend maintenance strategy for THS 2.2, namely identify chemical tobacco components which influence the sensory properties or the chemical composition of the THS 2.2 aerosol, further referred to as Critical to Quality Tobacco Attributes, or CQTAs, the extent to which they should be controlled, and at which stage in the manufacturing the controls should be implemented.

The secondary objective of the Blend Maintenance Study was to investigate the overall extent of variations in product performance driven by crop variability, to support the subsequent definition of a product performance range for THS 2.2 which forms the basis for assessing the impact of future product modifications and allows the establishment of the product performance comparability model.

3. STUDY DESIGN

(b) (4)

(see Figure 1). (b) (4)

(b) (4)

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Figure 3: Graphical Representation (b) (4)

Note: The colored dots representing the Lot Set DoE targets and the white dots representing the actual obtained levels.

(b) (4)

(b) (4) . All aerosol analyses were performed using the Health Canada Intense (HCI) regime (55 mL puff volume, 2s puff duration, 30s puff interval). The PMI-58 list of aerosol constituents were analyzed at Labstat International ULC, an independent ISO 17025 accredited tobacco testing laboratory; 1'400 tobacco sticks per batch were submitted for these analyses.

(b) (4)

(b) (4)

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(b) (4)

4. RESULTS

4.1. Control strategy definition

(b) (4) . The results are summarized in Figure 4.

(b) (4)

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Figure 4: (b) (4)

Note: (b) (4)

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4.2. Data reporting

4.2.1. Controlled Variables

The following measurements were performed and reported for further analyses:

a) (b) (4)
b)
c)
d)
e)
f)
g)

(b) (4)

4.2.2. Non-controlled variables

(b) (4)

4.2.3. Additional attributes

(b) (4)

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4.3. Data Evaluation

4.3.1. Assessment of Batches within Specification

(b) (4)

4.3.2. Attribute Selection

(b) (4)

(b) (4)

(b) (4)

(b) (4)

4.3.3. (b) (4)

(b) (4)

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(b) (4) (b) (4);

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(b) (4)

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(b) (4)

4.4. Statistical Model Results

A summary of aerosol attributes linked to tobacco attributes through model selection (b) (4) (b) (4) is provided in Table 1.

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Table 1: Summary of (b) (4)

(b) (4)

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In summary, the statistical models demonstrated that (b) (4) More specifically:

- (b) (4) . Figure 5 demonstrates how the statistical models have been used to (b) (4)
- (b) (4)
- (b) (4) (b) (4) .
- (b) (4)
- (b) (4)
- (b) (4)

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(b) (4)



Figure 5: Graphical representation (b) (4)

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(b) (4)

5. CONCLUSIONS

The results of the Blend Maintenance Study demonstrate that (b) (4)
(b) (4) The blend maintenance strategy was therefore formulated as follows:

(b) (4)

- (b)
- (b) (4)
- (b) (4)
- (b) (4)

6. APPROVALS

	Name	Role	Signature	Date
Author	Johannes Pijnenburg	Manager Heated Tobacco Product Substrates		23.Sept.2016
Author	Maxim Belushkin	Manager Scientific and QA Governance		23-SEP-2016
Owner	Markus Klein	Director Substrates Product & Process Development		23.Sept.2016
QA Review	Shelley Moores	Manager QA Assessment & Quality Systems		23-Sep-2016

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