

Technical Project Lead (TPL) Review: SE0015423

SE0015423: RAWBLACK KING SIZE SLIM	
Package Type	Booklet
Package Quantity	32 papers
Length	108 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Watermark Design "RAW"
Attributes of SE Report	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.01.30 16:19:32 -05'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering Branch Chief
Division of Product Science

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2020.02.03 16:31:38 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015423: RAWBLACK KING SIZE SLIM	
Product Name	ELEMENTS KING SIZE SLIM
Package Type	Booklet
Package Quantity	33 papers
Length	108 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Watermark Design "HBI"

The predicate tobacco product is a roll-your-own (RYO) rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 3, 2019, FDA received an SE Report from BBK Tobacco & Foods LLP dba HBI International. FDA issued an Acceptance letter to the applicant on September 10, 2019. On September 12, 2019, the Office of Compliance and Enforcement (OCE) held a teleconference with the applicant to clarify the predicate tobacco product name as of February 15, 2007. FDA received an amendment (SE0015475) in response to this request on September 12, 2019. FDA issued a Deficiency letter to the applicant on November 1, 2019. On November 5, 2019, FDA received an amendment (SE0015560) in response to the Deficiency letter.

Product Name	SE Report	Amendments
RAWBLACK KING SIZE SLIM	SE0015423	SE0015475 SE0015560

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific review completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Kaylene Charles on September 10, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

OCE completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated October 7, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated January 29, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A review was completed for Tobacco Product Master File (TPMF) (b)(4) by Sandra I. Salido on October 18, 2019, and January 2, 2020. Both reviews conclude the referenced information was previously evaluated in a chemistry review completed on April 22, 2019, by Megan Mekoli for SE Reports not subject of this review, and because the information was also relevant for this SE Report, no further review of the TPMF was necessary.

A chemistry review was completed by Sandra I. Salido on October 21, 2019. The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- A lower basis weight [REDACTED] for the rolling paper, which results in a decrease in (b)(4) content of the rolling paper by 15%
- Rolling paper: 32/booklet for the new tobacco product, and a starter page and warning page vs. 33/booklet for the predicate tobacco product, and only a warning page

The new and predicate tobacco products have different basis weights. The different basis weights can affect the paper porosity. The applicant submitted air permeability data that showed the cigarette paper of the new tobacco product has higher air permeability than the paper of the predicate tobacco product. Different air permeabilities could lead to different tar, nicotine, and carbon monoxide (TNCO) and benzo[a]pyrene (B[a]P) yields. The applicant submitted measured TNCO, TPM (total particulate matter), acetaldehyde, acrolein, and formaldehyde yields from test cigarettes made with the new and predicate tobacco products and the same tobacco filler. The measured TNCO yields from cigarettes made with the new tobacco product are not analytically equivalent but are lower than those from the cigarettes made with the predicate tobacco product. The smoke yields of acetaldehyde, acrolein, and formaldehyde from the cigarettes made from the new tobacco product and predicate tobacco

product are analytically equivalent. The lower and analytically equivalent TNCO and carbonyl smoke yields do not cause the new tobacco product to raise different questions of public health from a chemistry perspective. The increase in air permeability can also potentially impact B[a]P smoke yields. However, the physical characteristics of B[a]P as well as studies of cigarettes with different paper porosity levels indicate that the different air permeability of the new and predicate tobacco products is not anticipated to cause a significant increase in the B[a]P yields. There are also minor differences in papers per booklet between the new and predicate tobacco products. The new tobacco product has 32 papers per booklet and the predicate tobacco product has 33 papers per booklet. The number of rolling papers in the booklet does not impact the HPHCs of products made with the rolling papers. Also, with fewer rolling papers in the new tobacco product, there will be fewer RYO cigarettes made using the new tobacco product on a per booklet basis compared to the predicate tobacco product. Therefore, the different number of rolling papers does not cause the new tobacco product to raise different questions of public health. In addition, the new tobacco product has a starter page that is not present in the predicate tobacco product. The applicant provided testing data that showed there is no detectable chemical transfer from the starter page to the rolling papers. Therefore, the starter page does not cause the new tobacco product to raise different questions of public health.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Pritesh Darji on October 24, 2019 and January 2, 2020.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Rolling paper mass (↓11%)
- Rolling paper base paper basis weight (↓11%)
- Rolling paper base paper porosity (↑ based on test data and range limits)

Rolling paper mass decreased by 11% and base paper basis weight decreased by 11%. A decrease in base paper basis weight decreases the paper mass per unit area and is typically associated with paper that is more porous per unit area. Accordingly, a decrease in base paper basis weight may affect puff count and smoke constituents. The differences in paper mass and base paper basis weight may lead to a decrease in TNCO in the new tobacco product.

Rolling paper base paper porosity datasets provide an average value of (b) (4) in the new tobacco product and (b) (4) in the predicate tobacco product. The range limits of the new tobacco product ((b) (4)) are not encompassed by the predicate tobacco product range limits (b) (4). Therefore, an increase in the base paper porosity of the new tobacco product may lead to a decrease in TNCO, but an increase in B[a]P in comparison to the predicate tobacco product.

As a result, the impact of the change in rolling paper base paper basis weight, rolling paper mass, and base paper porosity on smoke constituents was deferred to chemistry.

Because the RYO paper does not contain any bands, target values and range limits of rolling paper band porosity, band width and band space are not needed for new and predicate tobacco products.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Kimberly Stratford on October 24, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- 11% decrease in base paper basis weight
- 218% increase in air permeability
- 0.03% decrease in the number of rolling papers per booklet

The new tobacco product shares similar physical characteristics and identical ingredients as the predicate tobacco product, including the paper dimensions, and paper ingredients and components. For example, the new and predicate tobacco products have the same levels of

(b) (4) Although differences between the new and predicate tobacco products (e.g., increase in air permeability) have the potential to impact mainstream smoke deliveries of certain HPHCs such as TNCO and carbonyls, as discussed in section 4.1, the applicant submitted HPHC data to show that the differences between the new and predicate tobacco products do not raise different questions of public health with respect to HPHCs and, therefore, are not expected to affect the toxicological profile of the new tobacco product compared to the predicate tobacco product.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Susana Addo Ntim on October 25, 2019, and December 17, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 27, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 27, 2019.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- Decrease in basis weight (11%), which results in a decrease in (b) (4) content by 15%
- Decrease in the number of rolling papers (0.03%): 32/booklet for the new tobacco product, and a starter page and warning page vs. 33/booklet for the predicate tobacco product, and only a warning page
- Decrease in mass (11%)
- Increase in air permeability (218%) and base paper porosity (based on test data and range limits)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health.

Decreases to the rolling paper mass and base paper basis weight in the new tobacco product as compared to the predicate tobacco product may lead to a decrease in TNCO in the new tobacco product. In addition, because the range limits of the new tobacco product are not encompassed by the predicate tobacco product range limits, an increase in the base paper porosity of the new tobacco product may lead to a decrease in TNCO and an increase in B[a]P in comparison to the predicate tobacco product. The applicant submitted measured TNCO, TPM, acetaldehyde, acrolein, and formaldehyde yields from test cigarettes made with the new and predicate tobacco products and the same tobacco filler. All HPHC data demonstrate analytically equivalent or lower smoke yields and thus do not cause the new tobacco product to raise different questions of public health. Chemistry also concluded that the physical characteristics of B[a]P as well as studies of cigarettes with different paper porosity levels indicate that the different air permeability of the new and predicate tobacco products is not anticipated to cause a significant increase in the B[a]P yields; therefore, smoke yield data was not requested for this constituent. The new tobacco product has one less paper per booklet than the predicate tobacco product. Fewer rolling papers in the new tobacco product booklet leads to fewer RYO cigarettes made using the new tobacco product on a per booklet basis compared to the predicate tobacco product, which does not cause the new tobacco product to raise different questions of public health. In addition, the new tobacco product has a starter page that is not present in the predicate tobacco product. The applicant provided test data showing no detectable chemical transfer from the starter page to the rolling papers. Although differences between the new and predicate tobacco products were identified, they are not expected to affect the toxicological profile of the new tobacco product compared to the predicate tobacco product. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015423, as identified on the cover page of this review.