

**Technical Project Lead (TPL) Review:**  
**SE0014701 and SE0014702**

<b>SE0014701: Republic El Rey Blue King Size</b>	
Package Type	Box
Package Quantity	200 Tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	35%
Characterizing Flavor	None
<b>SE0014702: Republic El Rey Blue 100MM</b>	
Package Type	Box
Package Quantity	200 Tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
<b>Common Attributes of SE Reports</b>	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Filtered Cigarette Tube
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2019.04.09 10:23:52 -04'00'

Kenneth M. Taylor, Ph.D.  
Chemistry 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: 2019.04.09 14:00:15 -04'00'

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

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## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

<b>SE0014701: Republic El Rey Blue King Size</b>	
<b>Product Name</b>	Top Regular 100MM
<b>Package Type</b>	Box
<b>Portion Count</b>	200 Tubes
<b>Length</b>	100 mm
<b>Diameter</b>	8.2 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>SE0014702: Republic El Rey Blue 100MM</b>	
<b>Product Name</b>	Top Gold 100MM
<b>Package Type</b>	Box
<b>Portion Count</b>	200 Tubes
<b>Length</b>	100 mm
<b>Diameter</b>	8.2 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None

The predicate tobacco products are roll-your-own (RYO) filtered cigarette tubes manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 3, 2018, FDA received two SE Reports (SE0014701 and SE0014702) from Republic Tobacco, LP. FDA issued Acknowledgement letters to the applicant on May 8, 2018. FDA issued an Advice/Information (A/I) Request letter on July 6, 2018. The applicant responded by submitting an amendment (SE0014837), which FDA received on July 31, 2018. FDA issued a Preliminary Finding (PFind) letter on November 5, 2018. The applicant submitted an amendment (SE0015051), which FDA received on January 11, 2019.

Product Name	SE Report	Amendment
Republic El Rey Blue King Size	SE0014701	SE0014837
Republic El Rey Blue 100MM	SE0014702	SE0015051

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Nicholas Hasbrouck on May 8, 2018.

The reviews conclude that the SE Reports are administratively complete.

## 3. COMPLIANCE REVIEW

The predicate tobacco products in SE0014701 and SE0014702 were determined to be substantially equivalent by FDA under SE0003200 and SE0003199, respectively, on September 26, 2013. Therefore, these products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the new tobacco products are 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 reviews dated July 31, 2018, October 22, 2018, and April 3, 2019, conclude that the new tobacco products are 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

Chemistry reviews were completed by Selvin Edwards on June 18, 2018, September 12, 2018, and March 13, 2019.

The chemistry reviews conclude that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

#### SE0014701

- Tipping Paper – 100% higher (b) (4); 445% higher (b) (4)
- Glue Seam/Filter – 117% higher (b) (4)
- Tipping Glue – 100% higher (b) (4)
- 35% increase in filter ventilation and 100% higher cigarette paper porosity

**SE0014702**

- Glue Seam/Filter – 184% higher (b) (4), 31% higher (b) (4)
- Tipping Glue – 100% higher (b) (4)
- Cigarette Paper – 100% higher (b) (4) 100% higher (b) (4)

Many of the ingredient quantities with large relative differences in the new tobacco products are present at added concentrations of less than 0.1% (1 mg/product) of the total product weight. Furthermore, the individual chemical ingredients that are included at levels greater than 0.1% of total product weight and display differences larger than 5% are primarily located in non-combusted components of the RYO injector tubes when the products are used as intended. Therefore, these ingredient differences are not expected to affect smoke chemistry. For SE0014701, the higher filter ventilation and cigarette porosity may decrease mainstream smoke and HPHC yields of the new tobacco products. The applicant submitted HPHC data demonstrating lower TNCO smoke yields for the new tobacco product compared to the corresponding predicate tobacco product. In addition, for SE0014702, ISO smoke yields for acetaldehyde, formaldehyde, acrolein, and benzene were provided to demonstrate that added (b) (4) does not cause the new tobacco product to raise different questions of public health. The mainstream smoke yields of acetaldehyde, acrolein, and benzene are lower in the new tobacco product by 3% - 11%; and equivalence testing shows that the 7% increase in formaldehyde is analytically equivalent to the predicate tobacco product. Based on this HPHC data, the addition of (b) (4) are not a concern.

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

**4.2. ENGINEERING**

Engineering reviews were completed by James Cheng on June 28, 2018, and by Drew Katherine on September 06, 2018.

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

**SE0014701**

- 16% decrease in filtered tube length
- 14% decrease in tipping paper length
- 28% decrease in filtered tube mass
- 100% increase in cigarette paper base paper porosity
- 28% decrease in filter denier per filament
- 35% increase in filter ventilation
- 7.3% increase in filter density
- 9.5% decrease in filter pressure drop
- 40% decrease in filter length

The differences in the design parameters of the new tobacco products can affect smoke constituent yields. Decreases in the filter tube length and mass, and denier per filament may decrease smoke constituents. Similarly, the increases in filter ventilation, filter density, (all of which increase filter efficiency) and cigarette base paper porosity should also reduce smoke constituents. For the new tobacco product in SE0014701, the decrease in the length of the tipping paper is offset by the 100% increase in the cigarette base paper porosity. Also, for the new tobacco product in SE0014701, the decrease filter pressure drop and filter length may reduce filter efficiency and cause an increase in tar and nicotine levels. However, the TNCO data for the new tobacco product for both ISO and CI smoking regimens are determined by the chemistry review to be either less than or analytically equivalent to the corresponding predicate tobacco product. This suggests that the lower pressure and filter length of the new tobacco product are not a concern.

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

#### 4.3. TOXICOLOGY

Toxicology reviews were completed by Ines Pagan on June 26, 2018, and by Luis DaSilva on September 24, 2018, and February 26, 2019.

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

##### SE0014702

- Increases in (b) (4) in the cigarette paper

For the new product in SE0014702, the cigarette paper has increases in some cigarette paper ingredients (e.g., (b) (4)) compared to the corresponding predicate tobacco product. The TNCO smoke yields for the new tobacco product are lower compared to the corresponding predicate tobacco product.

The applicant also provided HPHC measurements for formaldehyde, acetaldehyde, acrolein and benzene under ISO conditions to address concerns regarding the added (b) (4). The mainstream smoke yields of acetaldehyde, acrolein, and benzene are lower in the new product compared to the corresponding predicate tobacco product. Similarly, the 7% increase in formaldehyde for the new tobacco product was determined by the chemistry review to be analytically equivalent to that of the corresponding predicate tobacco product. Based on these HPHC results, the presence of (b) (4) are not a concern. Additionally, because these HPHCs are also pyrolysis byproducts of (b) (4), the increases in those cigarette paper ingredients do 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 products to raise different questions of public health from a toxicology perspective.

## 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Susan Addo Ntim on June 25, 2018, August 22, 2018, and February 15, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 24, 2018. The FONSI was supported by an environmental assessment prepared by FDA on October 24, 2018.

## 6. CONCLUSION AND RECOMMENDATION

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

### SE0014701

- Tipping Paper – 100% higher (b) (4) 445% higher (b) (4)
- Glue Seam/Filter – 117% higher (b) (4)
- Tipping Glue – 100% higher (b) (4)
- 16% decrease in filtered tube length
- 14% decrease in tipping paper length
- 28% decrease in filtered tube mass
- 100% increase in cigarette paper base paper porosity
- 28% decrease in filter denier per filament
- 35% increase in filter ventilation
- 7.3% increase in filter density
- 9.5% decrease in filter pressure drop
- 40% decrease in filter length

### SE0014702

- Glue Seam/Filter – 184% higher (b) (4) 31% higher (b) (4)
- Tipping Glue – 100% higher (b) (4)
- Cigarette Paper – 100% higher (b) (4) 100% higher (b) (4)
- Minor differences in (b) (4); in the cigarette paper

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new tobacco products have differences in cigarette paper (ingredients and design parameters), tipping paper (ingredients and design parameters), filter (design parameters) and tipping glue (ingredients). With the exception of cigarette paper, the ingredient differences occur in non-combusted components and are not expected to volatilize under intended conditions of use. The decrease in the length of the tipping paper, filter pressure drop, and filter length may reduce filter efficiency and cause greater HPHC smoke yields. However, these characteristic differences are offset by other design differences

including increases in cigarette base paper porosity, filter ventilation, and filter density. Additionally, TNCO yields are less for both new tobacco products in comparison to the corresponding predicate tobacco products; and ISO smoke regimen smoke yields for formaldehyde, acetaldehyde, acrolein and benzene are either reduced or analytically equivalent (SE0014702). Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco products in SE0014701 and SE0014702 were previously determined to be substantially equivalent by FDA under SE0003200 and SE0003199, respectively. Comparison of the new tobacco products to the grandfathered products (Top Gold King Size in SE0003199 and Top Regular King Size in SE0003200) reveals that the new tobacco products have the following differences in characteristics from Top Gold King Size and Top Regular King Size, the grandfathered tobacco products:

#### SE0014701

- 2% higher (b) (4) in cigarette paper
- 12.8% higher (b) (4) in cigarette paper
- 4.5% higher (b) (4) in filter
- 58% higher (b) (4) in cigarette paper
- 4% decrease in tipping paper length
- 3% decrease in filtered tube mass
- 50% increase in cigarette paper base paper porosity
- 5% decrease in filter denier per filament
- Addition of 35% filter ventilation (vs. no ventilation)
- 5.6% increase in filter pressure drop

#### SE0014702

- 17% higher (b) (4) in cigarette paper
- 11% higher (b) (4) in cigarette paper
- 57% higher (b) (4) in filter
- 198% higher K/Na citrate in cigarette paper

The increases in (b) (4) in the new tobacco products increase the burn rate and reduce puff count and tar. They can offset the lesser increases in the cigarette paper (b) (4) of both new tobacco products. Furthermore, the new tobacco products are either smaller and have increased porosity (SE0014701) or have increased (b) (4) in the filter (SE0014702) compared to the corresponding grandfathered predicate tobacco products. These changes are anticipated to reduce smoke HPHC yields in the new products. The applicant provided TNCO smoke yields to demonstrate that the differences in characteristics of the new tobacco products to the corresponding grandfathered predicate tobacco products are not a concern. The new tobacco product in SE0014701 has statistically significant 47% lower tar, 20% lower nicotine and 62% lower carbon monoxide smoke yields compared to the corresponding grandfathered

predicate tobacco product. The new tobacco product in SE0014702 has statistically significant 31% lower tar, 36% lower nicotine and 9% lower carbon monoxide smoke yields compared to the corresponding grandfathered predicate tobacco product. The lower TNCO smoke yields are favorable and do not indicate trends that the differences in ingredient quantities and design parameters would result in substantive increases in machine-measured HPHC deliveries using the ISO smoking regimen. Therefore, the differences in characteristics do not cause the new tobacco products to raise different questions of public health with respect to the corresponding grandfathered predicate tobacco products.

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

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

SE order letters should be issued for the new tobacco products in SE0014701 and SE0014702, as identified on the cover page of this review.