

**Programmatic Environmental Assessment for Marketing
Orders for New Waterpipe Tobacco
by Al Fakher Distribution USA, Inc.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

March 12, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Al Fakher Distribution USA, Inc.
Applicant Address:	14931 Gwenchris Court Paramount, CA 90723
Manufacturer Name:	Al Fakher Tobacco Factory, F.Z.E.
Product Manufacturing Location:	P.O. Box 20037, Free Zone Gate No. 4 Ajman, United Arab Emirates

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Original Product Names

New Product Name	STN	Original Product Name	STN
Al Fakher Plum Flavour 250 grams	EX0000978	Al Fakher Plum Flavour 250 grams	GF1908310
Al Fakher Golden Eskandarani Apple Flavour 250 grams	EX0000979	Al Fakher Golden Eskandarani Flavour 250 grams	GF1908339
Al Fakher Cherry with Mint Flavour 250 grams	EX0000980	(b) (4)	(b) (4)
Al Fakher Golden Strawberry Flavour 250 grams	EX0000981	Al Fakher Golden Strawberry Flavour 250 grams	GF1908338

Product Identification

Product Category:	Waterpipe Tobacco
Product Subcategory:	Waterpipe Tobacco Filler
Product Number per Retail Unit:	250 grams
Product Package:	Outer box with inner polyethylene pouch containing 250 g of waterpipe tobacco

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for four waterpipe tobacco products. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The original products are grandfathered products commercially marketed in the United States as of February 15, 2007. The new products are made by modifying the corresponding original products. These modifications are to the flavor additives (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- No new compounds or increased waste discharge is expected due to manufacturing the new products.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that the manufacturing facility is not within close proximity to any critical habitat of a threatened or endangered species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all applicable environmental regulations.

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all waterpipe tobacco. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility. The applicant stated that manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. The applicant stated that the new products have been manufactured at this facility for many years and that no new or increased amounts of compounds would be released due to manufacturing the new products.

The applicant stated that manufacturing the new products would not require any additional environmental controls for air emissions, water discharges, or solid waste disposal.

5.11 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing waterpipe tobacco at the listed facility, as many similar tobacco products would continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Air Quality

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other waterpipe tobacco products already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products of the original products and any other marketed waterpipe tobacco products; (2) the new products are expected to compete with, or replace, other currently marketed waterpipe tobacco; and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there would be no disproportionate impacts on minority or low-income populations.

6.4. Cumulative Impacts

The impacts from use of waterpipe tobacco products include exposure to secondhand smoke (SHS) produced from burned tobacco at homes, hookah bars, lounges, or anywhere else they are used. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011). While these studies focus on SHS from cigarette smoking, research suggests that SHS from waterpipe smoking may be worse due to higher concentrations of carcinogens, carbon monoxide, and other chemicals (Daher et al., 2010; Weitzman et al., 2016). Carbon monoxide poisoning has been reported for users of waterpipe tobacco products as well as non-users in environments where waterpipe tobacco was being consumed (Kocak et al., 2017), raising concerns for employees and non-smoking patrons of establishments where waterpipe tobacco is consumed.

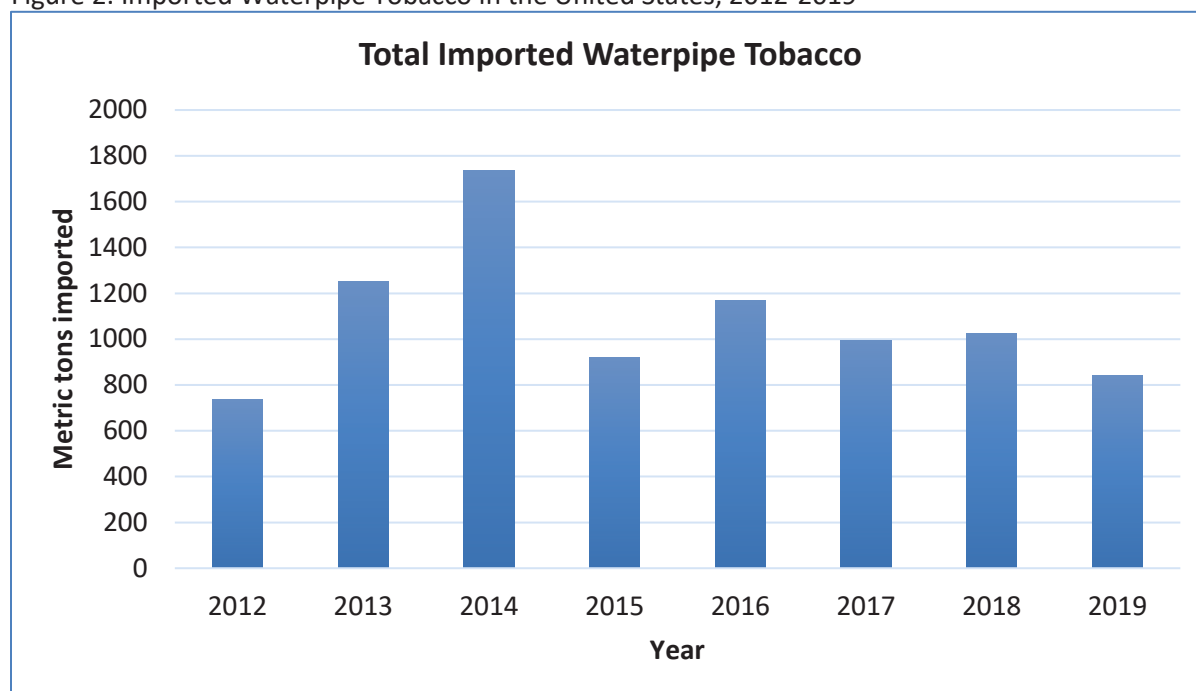
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

Although overall use of waterpipe tobacco does not appear to be changing based on import data since 2012¹ (Figure 2), use of waterpipe by youth and young adults is increasing (Grinberg, 2015). Researchers believe this increase is due to the false belief that waterpipe tobacco smoking is less addictive and harmful than cigarette smoking (Primack et al., 2008). Waterpipe tobacco smoking exposes users to nicotine, carbon monoxide, polycyclic aromatic hydrocarbons, volatile aldehydes, phenols, heavy metals and other constituents (Primack et al., 2016). Comparisons between cigarette smoking and waterpipe tobacco smoking suggests that users of waterpipe inhale as much as 120 times the tobacco smoke than cigarette users in a single session with increased concentrations of many components found in cigarette smoke. Waterpipe tobacco smoking is associated with various respiratory diseases, cancer, low birthweight, cardiovascular disease, and other health related issues (Waziry et al., 2017). This is especially concerning considering the prevalence of youth use (Primack et al. 2016). However, because marketing these products is not expected to increase overall consumption of waterpipe tobacco and waterpipe tobacco imports do not appear to be increasing, no cumulative environmental impacts from use are expected.

¹ U.S. International Trade Commission (ITC) statistical data available at: <https://dataweb.usitc.gov/trade/search/Import/HTS> . Accessed February 28, 2020.

Figure 2. Imported Waterpipe Tobacco in the United States, 2012-2019



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.5. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes, as many similar tobacco products would continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the new products. The chemicals in the new products are commonly used in other currently marketed waterpipe tobacco. Because the new products

are anticipated to compete with or replace other currently marketed waterpipe tobacco, the waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other waterpipe tobacco disposed of in the United States.

No changes in air quality from disposal of the new products' package materials would be expected because (1) the paper and plastic components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. The new products are not expected to change disposal conditions as (1) the disposal of the new products would be the same as the disposal of other waterpipe tobacco products that are currently marketed in the United States, and (2) there would be no anticipated increase in amount of waterpipe tobacco being disposed of as the new products are anticipated to replace similar marketed waterpipe tobacco.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the waterpipe tobacco and packaging from the new products because the chemicals in the new products would be used in currently marketed waterpipe tobacco. Furthermore, the new products would compete with or replace other waterpipe tobacco currently on the market.

7.5. Solid Waste

The Agency does not foresee the introduction of the new products would notably affect the current waterpipe tobacco and packaging waste generated from all waterpipe tobacco products. The waste generated due to disposal of the new products would be in the same manner as any other waste generated from any other waterpipe tobacco products marketed in the United States. The amount of waterpipe tobacco generated would be equivalent to the market projections (Confidential Appendix 2) and a portion of that would be littered.

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other waterpipe tobacco products in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7. Cumulative Impacts

Information on cumulative environmental impacts of disposal of tobacco and water from waterpipe smoking is scarce. However, users who smoke waterpipe tobacco at home discard the waste in various

places including trashcans, down the drain, in potted plants, in their yard, and in storm drains (Kaseem et al., 2019). This is concerning considering the various compounds that may leach out of the discarded tobacco, water, and charcoal after disposal including remaining heavy metals (Al-Kazwini et al., 2015).

Waterpipe tobacco contains ingredients used in cigarettes. While waterpipe tobacco is mainly heated but not combusted during use, similar types of toxic chemicals of discarded waterpipe tobacco and water may leach out to the environment as they leach out from cigarette butts. Discarded cigarette butts are known to leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). However, because marketing these products is not expected to increase overall consumption of waterpipe tobacco and waterpipe tobacco imports do not appear to be increasing, no cumulative environmental impacts from disposal are expected.

7.8. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of waterpipe tobacco and packaging, as many other similar tobacco products would continue to be disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Reviewer:

Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Kocak, A , Akbas, I , Cakir, Z. Carbon monoxide poisoning due to water pipe smoking: case series. *Journal of Emergency Medicine Case Reports*. 2017;8(2):27-30. Matt GE, Quintana PJE, Destailats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*. 2011;119(9):1218-1226.

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Primack BA, Sidani J, Agarwal AA, Shadel WG, Donny EC, Eissenberg TE. Prevalence of and associations with waterpipe tobacco smoking among U.S. university students. *Annals of Behavioral Medicine*. 2008;36(1):81–86.

U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic

Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

Waziry R, Jawad M, Ballout RA, Al Akel M, Akl EA. The effects of waterpipe tobacco smoking on health outcomes: an updated systematic review and meta-analysis. *International Journal of Epidemiology*. 2017;46(1):32-43.

Weitzman M, Yusufali AH, Bali F, Vilcassim MJR, Gandhi S, Peltier R, Nadas A, Sherman S, Lee L, Hong Z, Shearston J, Park SH, Gordon T. Effects of hookah smoking on indoor air quality in homes. *Tobacco Control*. 2017;26:586-591.

CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products

STN	Modification
EX0000978	<ul style="list-style-type: none"> • Reformulation of complex purchased flavor (b) (4) by changing the concentration of multiple compounds, removing multiple compounds, and adding multiple compounds
EX0000979	<ul style="list-style-type: none"> • Reformulation of complex purchased flavor (b) (4) by removal of (b)(4) and addition of (b)(4)
EX0000980	<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) (b) (4) • Decreased amount of complex purchased flavor (b) (4) • Increased amount of (b)(4)
EX0000981	<ul style="list-style-type: none"> • Reformulation of complex purchased flavor (b) (4) by removal of (b)(4) e and addition of (b)(4) • Reformulation of complex purchased flavor (b) (4) by changing the concentration of multiple compounds, removing multiple compounds, and adding multiple compounds

CONFIDENTIAL APPENDIX 2. Current Market Volumes and First- and Fifth-Year Market Volume Projections for the New and Corresponding Original Products and Percentage of Waterpipe Tobacco Imported to be Attributed to the New Products

Current market volume and first- and fifth-year market volume projections of the new products were compared to the total imported waterpipe tobacco into the United States.² For EX0000978, EX0000979, and EX0000981, the applicant stated that the original products are not currently on the market. For EX0000980, the applicant stated that the new and original products are currently being marketed simultaneously and that if the EX Request is granted, the new and original products would continue to be marketed simultaneously.

STN	Market Volume					
	Current Year		Projected Volume			
	Tobacco Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ³	First Year		Fifth Year	
			Tobacco Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ⁴	New Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ⁵
EX0000978	(b) (4)	█	█	█	█	█
Original to EX0000978						
EX0000979	(b) (4)	█	█	█	█	█
Original to EX0000979						
EX0000980	(b) (4)	█	█	█	█	█
Original to EX0000980	(b) (4)	█	█	█	█	█
EX0000981	(b) (4)	█	█	█	█	█
Original to EX0000981						
Total	(b) (4)	█	█	█	█	█

² The Agency used historical data regarding total import of waterpipe tobacco from 2012 to 2019 to mathematically estimate the total amount of waterpipe tobacco used in the United States. Using an average of the import data from 2012-2019, the forecasted use of waterpipe tobacco is 1084.8 metric tons.

³ Projected Market Occupation of the Product in the United States (%) = $\frac{\text{Projected Market Volume of the Product (metric tons of waterpipe tobacco)}}{\text{Projected Import of Waterpipe Tobacco in United States (metric tons)}} \times 100$

⁴ Ibid

⁵ Ibid