

**Programmatic Environmental Assessment for Marketing
Orders for New Waterpipe Tobacco Products**

Marketed by Al Fakher Distribution USA, Inc.

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

June 22, 2022

1. Applicant and Manufacturer Information

Applicant Name:	Al Fakher Distribution USA, Inc.	
Applicant Address:	14931 Gwenchris Court Paramount, California 90723	
Manufacturer Name:	Al Fakher Tobacco Factory, F.Z.E.	
Product Manufacturing Location:	(b) (4)	

2. Product Information

New Product (STNs), New Product Names, and Original Product Names

New Product STN	New Product Name	Original Product Name
EX0002185.PD1	Al Fakher Magic Love Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
EX0002186.PD1	Al Fakher Magic Love Flavour 1000 grams	Al Fakher Strawberry Flavour 1 kg
EX0002187.PD1	Al Fakher Magic Love Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams

Product Identification

Product Category:	Waterpipe Tobacco	
Product Subcategory:	Waterpipe Tobacco Filler	
Product Quantity per Retail Unit:	EX0002185	50 grams
	EX0002186	1000 grams
	EX0002187	250 grams
Product Package:	EX0002185	The package materials consist of an inner polypropylene pouch and an outer box.
	EX0002186, EX0002187	The package materials consist of an inner polyethylene pouch and an outer box.

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 three waterpipe tobacco filler 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 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.

(b) (4) The new products differ from the corresponding original products by the deletion, addition, and increase of different additives (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

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

(b) (4) . The applicant stated that manufacturing the new products will not (1) lead to changes in air emissions (2) require expansion of the manufacturing facility, or (3) require additional environmental controls or new permits for air emission and water discharges. The applicant also stated that the manufacturing facility is not within or in close proximity to threatened or endangered species habitats.

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 current and projected market volumes for the first- and fifth-years of marketing the new products in the United States (Confidential Appendix 2).

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will 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 will 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 heated tobacco chemical emissions from the new products will be released in the same manner as the heated tobacco chemical emissions of the original products and 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.

The impacts from use of waterpipe tobacco products include exposure to secondhand smoke (SHS) produced from heated 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.^{1, 2} 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.^{3, 4, 5} 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,⁵ raising concerns for employees and non-smoking patrons of establishments where waterpipe tobacco is consumed.

There is no safe level of exposure to SHS.^{6, 7} 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%.⁸
- 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.^{6, 7}
- SHS causes more than 40,000 deaths a year.⁸

Use of waterpipe tobacco by youth and young adults is increasing⁹ and researchers believe this increase is due to the false belief that waterpipe tobacco smoking is less addictive and harmful than cigarette smoking.¹⁰ Waterpipe tobacco smoking exposes users to nicotine, carbon monoxide, polycyclic aromatic hydrocarbons, volatile aldehydes, phenols, heavy metals and other constituents.¹¹ 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.¹² This is especially concerning considering the prevalence of youth use.¹¹ 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.

As of December 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws.¹³ Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.3. Environmental Justice

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

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of use of waterpipe tobacco, as many similar tobacco products will 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 will allow for the new products to be sold to consumers in the United States.

7.2. Air Quality

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

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 will 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 will be expected because (1) the packaging materials are commonly used in the United States, and (2) 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 tobacco products.

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 will be the same as the disposal of other waterpipe tobacco products that are currently marketed in the United States, and (2) there will 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 are used in other currently marketed waterpipe tobacco products. Furthermore, the new products will compete with or replace other waterpipe tobacco currently on the market.

Information on environmental impacts of disposal of water from waterpipe smoking is scarce. However, users who smoke waterpipe tobacco at home discard the water waste in various places including down the drain, backyard soil, and in storm drains.¹⁴ This is concerning considering the various compounds that may leach out of the discarded water after disposal including remaining heavy metals.^{15, 16}

Waterpipe tobacco contains ingredients similar to those used in cigarettes. While waterpipe products are mainly heated but not combusted during use as the case of cigarette smoking, similar types of toxic chemicals of discarded waterpipe water may leach out to the environment, potentially threatening human health and the environment, especially marine ecosystems.¹⁶ Individually, marketing these products is not expected to increase overall consumption of waterpipe (Confidential Appendix 2).

7.5. Solid Waste

Like cigarette butts, the environmental toxicity of discarded waterpipe tobacco is not well studied, but it is likely that discarded waterpipe tobacco may leech out into water, potentially affecting human health and the environment, especially marine ecosystems.¹⁷ The chemicals in discarded tobacco can be the original chemicals in the unsmoked tobacco or the pyrolysis and distillation products produced during use. Airborne emissions from used tobacco after disposal depend on the environmental conditions and the chemicals in the used tobacco. These emissions can be influenced by several factors, such as the brand, flavorings and other ingredients in the tobacco filler, types of tobacco, and extent of use. Emissions from disposal of the charcoal are unlikely to be of concern since the majority of charcoal will be used up in the smoking process. Additionally, air emissions from the disposed waterpipe water seem unlikely as those chemicals will likely remain in the water.

The Agency does not foresee the introduction of the new products will 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 will be disposed of 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 waste generated will be equivalent to the market projections (Confidential Appendix 2) and a portion of that will 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 will 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 will be no disproportionate impacts on minority or low-income populations.

7.7. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of disposal of waterpipe tobacco and packaging, as many other similar tobacco products will 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:

Carla Figueroa, M.S., Center for Tobacco Products
Education: M.S. in Biotechnology
Experience: Six years in various scientific activities

Expertise: Water quality, wastewater treatment, regulatory compliance

Reviewer:

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

Education: Ph.D. in Environmental Science and Management

Experience: Six 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

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Confidential Appendix 1. Changes in the New Products as Compared with the Corresponding Original Products

STN	Modifications
EX0002185	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavors (b) (4) • Increase in the quantity of (b) (4)
EX0002186	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavors (b) (4) • Increase in the quantity of (b) (4)
EX0002187	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavors (b) (4) • Increase in the quantity of (b) (4)

Confidential Appendix 2. First- and Fifth-Year Market Volume Projections for the New Products.

The applicant stated that if the EX requests are granted, only the new products will be manufactured for commercial distribution in the United States.

STN	Projected Market Volume	
	First-Year (Metric Tons)	Fifth-Year (Metric Tons)
EX0002185	(b) (4)	
EX0002186		
EX0002187		
Total		