

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 7/9/2024-7/17/2024* FEI NUMBER 1081922			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Rafael Romeu, Assistant Manager					
FIRM NAME Krispy Kreme Doughnut Corporation		STREET ADDRESS 8425 N Florida Ave			
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33604-3035		TYPE ESTABLISHMENT INSPECTED Mnaufacturer			
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Your hazard analysis did not identify a hazard that required a preventive control. Specifically, your hazard analysis for "Krispy Kreme Food Safety Plan RTE Yeast & Cake Doughnut Varieties (OG Rings, Shells, and Cakes)" did not identify recontamination with environmental pathogens as a hazard requiring a preventive control at the following steps after the fryer: 1. In-line Glaze Equipment 2. (b) (4) 3. (b) (4) 4. Metal detector					
OBSERVATION 2 You did not implement your sanitation preventive control, monitoring and verification procedures. Specifically, your hazard analysis for "Krispy Kreme Food Safety Plan RTE Yeast & Cake Doughnut Varieties (OG Rings, Shells, and Cakes)" identifies recontamination with environmental pathogens as a hazard requiring a sanitation preventive control at (b) (4) step. You make ready to eat products that are exposed to the environment after the fryer step, including in-line glaze, (b) (4), (b) (4) and packaging. You do not have records for the sanitation monitoring activities performed. You provided with (b) (4) Sanitation & Preventive Maintenance Checklist Booklet" form intended to be used to record the sanitation activities, however, this form has not been filled out (b) (4) the sanitation activities have been performed. Additionally, your hazard analysis for "Krispy Kreme Food Safety Plan RTE Yeast & Cake Doughnut Varieties (OG Rings, Shells, and Cakes)" identified sanitation verification and Environmental swab Program as a Preventive Control for the recontamination with environmental pathogens potential hazard. Your "Environmental Monitoring Program for Foodborne Pathogens for (b) (4)					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Narahi J Alvarez Alcazar, Investigator Carol S Davis, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> DATE ISSUED 7/17/2024 Narahi J Alvarez Alcazar Investigator Signed By: Narahi J. Alvarez Alcazar-6 Date Signed: 07-17-2024 13:58:24 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Narahi J Alvarez Alcazar, Investigator Carol S Davis, Investigator	DATE ISSUED 7/17/2024 Narahi J Alvarez Alcazar Investigator Signed By: Narahi J. Alvarez Alcazar-6 Date Signed: 07-17-2024 13:58:24 X
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Areas (Zones (b) (4)) stated that environmental samples to be tested for Listeria and Salmonella will be collected (b) (4). No environmental samples have been collected for Listeria or Salmonella.			
OBSERVATION 3 You did not implement your process preventive control and monitoring procedures. 1. Specifically, your hazard analysis for "Krispy Kreme Food Safety Plan RTE Yeast & Cake Doughnut Varieties (OG Rings, Shells, and Cakes)" identifies Bacteria pathogens-presence/ growth/ toxin production due survival of lethal treatment ("Product Lethality") as a hazard requiring a process preventive control at the Frying step. You make ready to eat products that are fried and according to your hazard analysis the (b) (4) temperature of the product must reach (b) (4) °F or greater. According to your hazard analysis, visual checks of (b) (4) temperature (b) (4), (b) (4) temperature, (b) (4) time in (b) (4) and (b) (4) temperature of the donut will be taken (b) (4) and documented in the SOP CCP form on (b) (4). You stated that you only perform visual checks of the (b) (4), but no records are maintained. Additionally, the (b) (4) temperature, (b) (4) time in (b) (4) and (b) (4) temperature of the donut are not taken and recorded. 2. Specifically, your hazard analysis for "Krispy Kreme Food Safety Plan RTE Yeast & Cake Doughnut Varieties (OG Rings, Shells, and Cakes)" identified metal as a hazard requiring a process preventive control at the Metal Detection step. You make ready to eat products that are exposed to metal mixer, and extruder/ cutting operations. According to your hazard analysis, visual inspection of the metal detector should be performed at least (b) (4). You stated those checks are not performed as no metal detector has been installed in your processing line.			
OBSERVATION 4 You did not exclude pests from your food plant to protect against contamination of food. Specifically, - On 7/9/2024, two live flies were observed in the warehouse area and landing on cleaned trays stacked on a (b) (4) rack. The trays are food contact surfaces used in the production of the doughnuts. - On 7/15/2024, one live fly was observed in the processing line near the RTE packaging area. On 7/9/2024, a 1/2" gap was observed between the loading bay door at the warehouse area and the floor.			
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OBSERVATION 5 You did not take a reasonable measure or precaution related to personnel practices. Specifically, during the inspection on 7/9/2024 employees were observed not following the good manufacturing practices as outlined in your procedures. 1. Employee working at the beginning of the processing line failed to remove jewelry (necklace) which might fall into the product. 2. Conveyor belt control panel (b) (4) the packaging step was observed with black build-up. Employee was observed to be touching the control panel and then continue to pack the RTE doughnuts without washing their hands and changing gloves. 3. The hand washing sink next in the processing area next to the warehouse door did not have warm running water on 7/9/24 at the start of the walk through.			
OBSERVATION 6 Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against contamination. Specifically, the following utensils and equipment were not designed to be adequately cleaned or maintained: 1. Cardboard pieces being used to hold conveyor belt in place before the packaging step. On 7/9/2024, RTE doughnuts were observed to have direct contact with the cardboard pieces while they were conveyed for packaging. 2. Stagnant dirty water was observed in the scoop compartment of the (b) (4) bins used to store the doughnut ingredients yeast, and stabilizer. These scoops have direct contact with the stagnant water, and they are used to grab ingredients from the bins to the mixer. 3. Cleaned (b) (4) trays were observed with food residue and old pieces of tape in the (b) (4) rack. 4. Thermometer with dry buildup of dough was observed and placed next to box cutter knife with rust. On 7/9/2024, this thermometer was used to measure the temperature of the dough after the dough (b) (4) step. The thermometer was not cleaned and sanitized before use.			
*DATES OF INSPECTION 7/09/2024(Tue), 7/15/2024(Mon), 7/17/2024(Wed)			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."