

USDA, FDA, NSF, and CFIA Regulations Affecting the Use of K-Flex Insulation Products

The **USDA** (United States Department of Agriculture) regulates products used in food or meat processing plants. This includes breweries, meatpacking plants, dairies, fruit processing plants, vegetable processing plants, and juice packing plants. Prior to 1994, the USDA reviewed product formulas for compliance with their regulations. However, due to government cutbacks, this program is now a self-certification program. K-Flex USA insulation products (NBR/PVC based elastomeric insulation and K-Flex® 374 protective coating) meet the guidelines of the USDA program. The program guidelines are defined as follows:

K-Flex USA insulation products are approved for use in federally inspected meat and / or poultry establishments as long as it is unexposed. All exposed insulation materials must be covered with an approved jacket.

The topics of “Unexposed Insulation” and “USDA Approval” are explained in a letter written by Dr. Karen M. Wesson, DVM. Dr. Wesson was the Director of Facilities for the Equipment and Sanitation Division of the USDA. The letter is dated June 13, 1996.

Following are excerpts from Dr. Wesson’s letter.

“The Food Safety and Inspection Service (FSIS) and Facilities, Equipment and Sanitation Division (FESD) do not review or issue letters of approval for unexposed insulation materials. A letter of approval or acceptance is not required to be furnished to the FSIS inspector for the use of unexposed insulation materials in federally inspected meat and poultry establishments. However, they must meet the following requirements prior to their use in federally inspected meat or poultry establishments:

1. The unexposed insulation material must be installed and maintained in a sanitary manner acceptable to the FSIS inspector in charge.
2. The FSIS inspector in charge must be notified prior to installation of the unexposed insulation material as to the time and place the unexposed insulation material will be installed.”

The **FDA** (Food and Drug Administration) recognition program is similar to that of the USDA, only their restrictions are much more stringent. The FDA does not test and approve or reject particular rubber compounds. To meet the requirements of the FDA, products must be manufactured from a list of ingredients established by the FDA. The list is published in 21CFR-177.2600 and is commonly referred to as the “white list.” This list identifies raw materials that can be used and in what quantities. FDA recognition is only applicable in situations where the insulation actually comes in contact with the food item such as bottles, caps, seals etc. Insulation applications that would require FDA guidelines are very few. Our insulation products do not meet the requirements of FDA.

NSF (National Sanitation Foundation) is a non-government agency; similar to UL that certifies products for a wide range of applications (i.e. those associated with potable water, freezers, dishwashers, etc). K-Flex Clad® WT and Clad® WT NS have been approved by NSF for standard 169, “Special Purpose Food Equipment and Devices”. On some occasions, generally when K-Flex insulation is used as a gasket, the product formulation must be submitted to NSF where it is evaluated in conjunction with the completed unit for the specific application.

The **CFIA** (Canadian Food Inspection Agency) regulates products used in Canadian food and meat processing plants, and has recently changed the requirements for mechanical insulation used in those plants. On July 2, 2014 the Government of Canada repealed the requirement for pre-registration of construction materials, packaging materials and non-food chemicals used in federally registered meat establishments through changes to the Meat Inspection Regulations, 1990. With amendments to the Egg Regulations and Fish Inspection Regulations, there is no longer a similar regulatory requirement for fish, seafood and eggs. In addition, no regulations exist for dairy, fresh fruits and vegetables, non-meat manufactured and processed products. The CFIA no longer requires industry to pre-register construction materials, packaging materials, non-food chemicals and working apparel. Therefore, the CFIA will no longer be pre-approving these materials. The reference listing will continue to be available on the CFIA website as a reference only for a period of two years.

Note: The reference listing was still accessible as of 06/16.