

The Continuing Evolution of Food Grade Lubricants

By

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For many years, the United States Department of Agriculture's Food Safety and Inspection Service Division (USDA/FSIS) reviewed the formulations of maintenance and operating chemicals, including lubricants, for use in official meat and poultry establishments that operate under USDA inspection. This "Prior Approval Program" as it came to be known, was the industry standard for determining food-grade lubricants. The USDA/FSIS' *List of Proprietary Substances and Nonfood Compounds* was the only source for food-grade and non-food-grade lubricant reference for food and beverage processors worldwide. It listed lubricants in categories labeled H-1, H-2, H-3 and P-1.

True food-grade, USDA H-1 authorized lubricants, are compounds that are permitted for use on equipment in locations in which there is potential exposure of the lubricated part to food. These instances are referred to by the USDA/FSIS as incidental contact.

USDA H-2 authorized lubricants, usually containing non-toxic ingredients, may be used in food-processing plants on equipment in locations in which there is no possibility of the lubricant or lubricated part contacting edible products.

The USDA H-3 category refers to water-soluble oils. The machined part has to be cleaned and free of the emulsion before re-use.

Finally, the USDA P-1 category refers to lubricants that are to be used in accordance with the conditions set forth in the USDA's letter of acceptance. These lubricants should not be used in a food or beverage processing plant.

The USDA/FSIS made its determination about lubricants based on the various Food and Drug Administration (FDA) Codes in FDA Title 21 Code of Federal Regulations (CFR.) There are five codes in FDA Title 21 that dictate approval for ingredients for use in lubricants that may have incidental contact with food. See exhibit A for explanation of those FDA Title 21 Codes.

The USDA/FSIS' Prior Approval Program for Proprietary Substances and Nonfood Compounds was very effective. It served as a "watchdog" for the lubricants industry and protected the consumer against harmful substances that had the potential to contaminate food and beverage products.

But, in February 1998, things changed!

In an official announcement published in *FEDERAL REGISTER*, the USDA/FSIS said it was eliminating the Prior Approval Program. It pointed to the evolution of Hazard Analysis Critical Control Point (HACCP) programs in which biological, chemical and physical hazards had to be monitored by food and beverage processors and both FDA and USDA inspectors. Lubricants are a potential chemical hazard in HACCP programs. Also, it estimated that between \$150,000 and \$187,000 in USDA administrative costs could be saved by eliminating the Prior Approval Program. There were no fees involved for manufacturers that submitted their products for potential USDA authorization.

Food-grade FDA ingredient-compliant lubricants are significant in HACCP programs because if the food or beverage processor uses only H-1 food-grade lubricants, then the lubricants are not considered as potential chemical hazards.

In addition to HACCP compliance, one of the solutions suggested by the USDA/FSIS was for users of food-grade lubricants to seek “letters of guarantee” from their suppliers, which would certify that the lubricants being used were manufactured with FDA Title 21-approved ingredients.

The elimination of the Prior Approval Program left the international lubricants industry in a quandary. There was a defined requirement for food-grade lubricants in HACCP plans, for instance. Lubricant manufacturers knew that food-grade lubricants must be manufactured with FDA Title 21-approved ingredients in order to eliminate them as potential chemical hazards in HACCP programs. But, what organization could be the industry “watchdog” to ensure compliance?

Three organizations came forth with plans for food-grade lubricant authorization and monitoring: The National Sanitation Foundation (NSF,) Underwriters Laboratory (UL) and a Joint Working Group from three lubricant industry professional associations: The National Lubricating Grease Institute (NLGI,) The European Lubricating Grease Institute (ELGI) and the European Hygienic Equipment Design Group (EHEDG.)

The NSF, an internationally respected, non-profit consumer products monitoring organization, developed an authorization program that mirrors the USDA/FSIS program and is guided by Title 21 of the FDA’s Code of Federal Regulations. NSF registration is a formal procedure in which it reviews the lubricant formulations and certifies that they are in compliance with the various FDA Title 21 regulations. Once products are registered, the lubricant manufacturer may use the “NSF-registered” logo in its

promotional literature and trade advertising. Also, a very important feature of the NSF's program is that formulations and products are continually monitored for efficacy. In the USDA/FSIS system, lubricant manufacturers were "on their honor" to re-submit products if there were formulation modifications. There are fees for NSF evaluation and registration so the burden is on the manufacturer to make sure that its products are formulated with FDA Title 21-approved ingredients. Product submissions cannot be whimsical because of the justifiable fees involved. Lubricant consumers may gain easy access to the NSF's registered lubricants and chemicals list by logging on to its website www.nsf.org/usda/listings.asp. Like the USDA/FSIS designation, the NSF designates food-grade lubricants, i.e., those lubricants approved for incidental contact, as NSF/H-1 registered.

Underwriters Laboratory has not been aggressive in defining its lubricants and chemicals authorization program although it has organized several informational meetings to which lubricant and chemical manufacturers were invited.

The NLGI/ELGI/EHEDG Joint Food Grade Lubricants Working Group has been very active in drafting an authorization program for food-grade lubricants. Like the NSF, the Group's program mirrors the former USDA/FSIS authorization program and the ingredients used to manufacture food-grade lubricants must be FDA Title 21-approved compounds. The Group's plan is to obtain a German Government-sanctioned DIN standard and then use the DIN standard as a basis for an ISO (International Standards Organization) standard. The Group also acknowledges the importance of HACCP programs which call for the use of FDA ingredient-compliant H-1 food-grade lubricants.

Equally important as industry monitoring are the continued technological developments in the formulations of H-1/food-grade lubricants which must provide

lubrication protection for food and beverage-processing machinery worth hundreds of thousands of dollars. Both petroleum-based and synthetic lubricants are available to effectively do the job.

Petroleum-based H-1/food-grade lubricants are developed with either technical white mineral or USP-type white mineral oil. USP mineral oils are the purest of all white mineral oils, and are the most oxidation stable, providing optimum lubrication against all other white mineral oils. FDA-compliant ingredients are added to the formulations to increase anti-wear capabilities, improve oxidation resistance and prevent rust and corrosion.

Synthetic H-1/food-grade lubricants available are primarily polyalphaolefin (PAO)-based fluids. They provide significant oxidation resistance versus petroleum-based H-1 food-grade oils. They also provide significantly better cold temperature operating capability. In combination with food-grade additives, PAO-based food-grade H-1 fluids are outstanding lubricants for air compressors, oil recirculating systems, hydraulic systems and gear reducers. Their initial high cost is more than justified by their long-range performance. Fluids that are 100 percent PAOs significantly outperform the PAO plus polymer semi-synthetic fluids.

Polyalkylene glycol-based (PAGs) H-1 food-grade synthetic fluids are becoming very popular for applications where temperatures exceed 400° F/204° C up to 600° F/316° C. Bearings, chains and gear reducers subjected to these temperatures are candidates for polyalkylene glycol H-1 fluids.

Polyolester (POE) food grade synthetic fluids are very popular for high temperature oven chain lubrication in the baking industry.

H-1 food-grade greases may be either petroleum-based or synthetic. Aluminum complex is the most common thickener for today's food-grade greases, and produces a very shear stable product. Aluminum complex-thickened greases also can withstand elevated temperatures. They are also very water resistant, which is vital for food and beverage-processing equipment because of post shift equipment wash downs.

Recent developments with calcium sulphonate thickeners in combination with titanium dioxide for anti-wear protection and synthetic PAO-based fluids have expanded the capabilities of H-1/food-grade greases. Calcium sulphonate thickened greases in combination with USP and technical white mineral oils are also available.

Exhibit A displays the relevant FDA Title 21 codes to which all petroleum-based and synthetic fluids and other ingredients must comply.

Exhibit A

F.D.A. CODES (CFR) FOR LUBRICANTS WITH INCIDENTAL FOOD CONTACT

21.CFR 178-3570	Ingredients used to manufacture H-1 lubricants must comply with this code.
21.CFR 178-3620	Technical White Mineral Oil as a component of non-food articles intended for use in contact with food.
21.CFR 172-878	USP White Mineral Oil for direct contact with food.
21.CFR 172-882	Synthetic isoparaffinic hydrocarbons, i.e., PAO base stocks.
21.CFR 182 with 9 subheadings	Substances Generally Recognized As Safe, e.g., zinc oxide and tocopherols (Vitamin E.)

The most important aspect in the evolution of food-grade lubricant technology is that H-1/food-grade lubricants can now effectively handle every machinery lubrication application at a food and beverage-processing plant. This produces lubricant inventory consolidation, is good for the food and beverage-processing plant employees, and—most important—gives added protection to the ultimate consumer.