



## Food Grade Lubricant Safety

Human beings eat to survive. They also center their celebrations, traditions and personal time around food. This makes food safety extremely important. Consumers place an immense amount of trust in the providers of the food they purchase.

Food and beverage processing plants have regulations above and beyond general industry that they must consider when purchasing lubricants for their production equipment. These lubricants are often called “food grade” lubricants, although that just means they are acceptable for incidental food contact. The



equipment operators and maintenance personnel at these facilities are aware that they must use lubricants that meet the regulatory requirements. At the same time, they also have a desire to properly lubricate their equipment so that it continues to operate reliably and resist wear.

It can be a balancing act to ensure food safety, be compliant with regulatory requirements, and properly maintain peak lubrication performance. Over the years, programs have been developed to help food plant maintenance staff simplify the lubricant selection process so they can meet regulatory requirements, ensure food safety and protect their equipment. The best way to become acquainted with those programs is to review the background, history and current state of these programs.

### Background

The United States Department of Agriculture (USDA) created the original food grade lubricant designations: H1, H2 and H3. The approval of a lubricant and its registration in one of these categories depended upon the list of the ingredients.

- H1 lubricants are used in food-processing environments where there is the possibility of incidental food contact.

- H2 lubricants are used on equipment and machine parts in locations where there is no possibility of contact.
- H3 lubricants are typically edible oils used to prevent rust on hooks, trolleys and similar equipment.

Deciding whether there is a possibility of contact is often difficult; therefore, many have erred on the side of safety recommending H1 lubricants over H2 lubricants.

NSF International, one of the main approval bodies for incidental food contact lubricants, defines food grade in this way: “During normal operations, there is a possibility of a lubricant making minor contact with food. Since food grade lubricants are technically not a food ingredient, this incidental contact cannot lead to the contamination of the food.”

For a lubricant to be registered for incidental contact, the product must be formulated in accordance with the U.S. FDA Code of Federal Regulations (CFR) Title 21, Section 178.3570. This CFR provides a specific list of chemical compounds and additives allowed. In addition, it requires:

- The lubricant must be odorless, colorless and tasteless.
- A limit of 10 parts per million (ppm) for lubricant base oils, e.g., mineral oil, that can be present in food if incidental contact should occur.
- The lubricant must be registered as H1 or certified to ISO 21469 to be considered food grade.

### History

For more than 3,000 years, followers of Jewish and Muslim religious traditions have regulated the selection and handling of the foods they prepare and eat. It is likely that some of these traditions provided the basis for currently established regulatory rules for food selection, preparation and storage.

#### 1882 – USDA H1, H2, H3

One of the first regulatory agencies for the food industry was the U.S. Department of Agriculture (USDA), established in 1882. The inspection





arm of the former USDA authorization program was operated by the Food Safety Inspection Service (FSIS). Only compounds on the USDA list were permitted inside meat and poultry processing plants. Food processors retained “authorization letters” for every product they used, or they maintained a copy of the USDA listing book. The range of nonfood compounds authorized by the USDA included cleaners, sanitizers, lubricants and products with incidental food contact, such as tripe processing agents, defoamers and tattoo inks. Nonfood compound formulations were required to comply with the U.S. FDA Code of Federal Regulations (CFR) Title 21.

**1924 & 1974 – Kosher Pareve and Halal**

The Orthodox Union was established 1898 and it was the first organization to establish a Kosher food certification agency in 1924. (“Pareve” is the designation OU uses to certify industrial lubricants.) The first recorded Halal certifications are traced back to 1974, and certifications increased dramatically after 1993 when processed foods were added for review and certification.



**1999 – NSF Non-Food Registration**

USDA posted notices in the Federal Register on Aug. 25, 1997, and on Feb. 13, 1998, that it terminated its authorization program. USDA would no longer provide product authorization service but agreed to act in an advisory capacity, if possible, to assist in the transition from the “Command and Control” strategy to a performance-based Hazard Analyses and Critical Control Points (HACCP) system. This change in philosophy also resulted in the termination of the FSIS Food Processing Equipment Approval Program.

For approximately one year, companies like LE self-certified their H1 and H2 products formulations using the former USDA FSIS CFR Title 21 178.3570 standards – the FDA GRAS (generally recognized as safe) list. Many non-food

compound manufacturers and food processors began to express concern to USDA over the loss of a centralized approval program. They were afraid of misinterpretations or downright dishonest self-certifications being placed into the food processing plants.

In 1999, NSF International staff met with USDA staff to discuss the possible continuation of the program. (NSF was founded in 1944 as the National Sanitation Foundation and changed its name to NSF International in 1990.) USDA suggested that NSF meet with key organizations in the industry to determine elements of the program. This included the Independent Lubricant Manufacturers Association (ILMA), the International Sanitary Supply Association (ISSA), the Chemical Specialties Manufacturers Association (CSMA), as well as representatives from many of their member companies. These meetings provided valuable input into the current structure of the NSF Registration Program. NSF received strong support for continuing the lapsed USDA program.



The registration program was launched in late 1999 and received considerable attention in the industry. NSF held industry forums and user forums in 2000 to determine the elements of the registration program most important to all stakeholders. The greatest needs were seen as remaining current with listings, as well as the guidelines document. The best mechanism to accomplish this was seen as the NSF Nonfood Compounds Steering Committee, which was tasked with providing advice and counsel on the guidelines, review process, listings and policies that govern registration.

A list of approved product registration certificates can be found on the NSF Website. LE has registered several H1 products with NSF but chose not to do this with its H2 products. Instead, LE self-certified its H2 lubricants, which can be used in food plants but only on applications where there is no chance of incidental food contact.

## 2006 – ISO 21469

A newer standard for food grade lubricants – ISO 21469 – emerged in February 2006, when it was approved and made available by International Organization for Standardization (ISO).



Some lubricant manufacturers have obtained the ISO 21469 approval, which requires additional steps beyond the more common NSF product registration. Those companies will use it as a marketing tool to claim superiority, but in most of the world it is not a required standard for food processors. Regulatory bodies in a few countries are starting to require food plants to use ISO 21469-certified lubricants; however, most countries continue to use the NSF product registration, as it is well recognized and respected.

## Current State

### Comparison: NSF H1 vs. ISO 21469

The decision for food processing lubricant end users becomes whether to use ISO 21469-approved products or NSF-registered products. A comparison of the two should help with this decision. Like the pre-existing NSF H1, H2 and H3 designations, ISO 21469 is about trying to ensure that consumers are protected from the deleterious effects of contamination of food and food-related products with the lubricant. However, there are a few important distinctions that can be pointed out:

- ISO 21469 only addresses products intended for “incidental contact” (so-called H1 products). It does not cover the NSF H3 category of lubricants where product contact is inevitable, e.g., a meat hook, nor does it address H2 lubricants.
  - Unlike NSF’s H1 designation, which addresses the potential toxicological, carcinogenic and mutagenic effects of the lubrication by checking the lubricant’s ingredients against a list of approved food-safe products (per 21.CFR 178.3570), ISO 21469 addresses the whole process of lubricant design, manufacturing, packaging and transportation.
- The key to achieving ISO 21469 certification is conducting a thorough “hygiene risk assessment,” which addresses the chemical safety of the lubricant (non-toxic, non-carcinogenic, non-mutagenic), as well as the potential for physical risk from the ingestion of dirt, dust or metals; and the biological risk due to the formation of pathogens or other biologically active agents from long-term storage, spoilage, etc.
  - Both the NSF H1 and ISO 21469 designations help to ensure that a lubricant and its ingredients are “safe” in the event of incidental food contact. ISO 21469 adds another layer of oversight beyond just the formulation of a given product. It also includes an audit of the manufacturing process, and quality control applied to the lubricant formulation, manufacturing, distribution and storage.





### **Bottom Line**

ISO 21469 is a voluntary standard; therefore, it is not required that food processors use products certified to this standard, nor that food grade lubricant manufacturers go through this process. Many, like LE, have yet to do so. NSF continues to provide the conventional H1, H2 and H3 designations for food-grade lubricants. Other organizations can provide auditing services required to obtain ISO 21469.

LE's incidental food contact lubricants and processes have been certified to meet both Kosher and Halal requirements. Like ISO 21469, these certifications require onsite audits of the product formulas, raw material storage, processes, finished product storage, and plant cleanliness. As a result, these products are exposed to the same set of requirements necessary for ISO 21469. LE is confident that the use of the LE food machinery lubricants on food processing equipment will not sacrifice food safety or contradict religious requirements, yet still provide outstanding equipment lubrication protection and reliable operations.



### **Reference**

- [www.machinerylubrication.com/Read/22919/ISO-21469-food-safety](http://www.machinerylubrication.com/Read/22919/ISO-21469-food-safety)
- [www.machinerylubrication.com/Read/31126/food-grade-lubricants](http://www.machinerylubrication.com/Read/31126/food-grade-lubricants)
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