



# Food grade lubricants and their regulation

Voluntary standards and third-party registration programs continue to grow regarding food safety for lubricants.

## KEY CONCEPTS

- In the U.S., food-grade lubricant products must be formulated in accordance with Title 21 Code of Federal Regulations (21CFR) 178.3570.
- Third-party registration is used widely by food-grade lubricant manufacturers around the world to show compliance.
- H1 registered and ISO 21469 certified lubricants help food processors mitigate risks and comply with HACCP plans.

**THE FOLLOWING ARTICLE IS BASED** on an STLE University Webinar presented by Ashlee Breitner, business unit manager of the NSF International Consumer Products and Nonfood Compounds programs, on March 18, 2015.

NSF International works with products that encompass many aspects of food production. Its mission is to protect and improve public health and safety, which is accomplished by pulling together industries, consumers and regulators to create common grounds such as industry standards, product standards, protocols and guidelines. It also tests and certifies products toward those common sets of ground.

It works with products such as lubricants but also with cleaners, water treatment chemicals and other chemical processing agents that aren't supposed to come into contact with food or be added into the food supply during production processes.

NSF provides services to thousands of organizations in 150 countries, conducting safety audits for the food, water and consumer goods industries, writing more than 80 standards to promote the safety of food, drinking water, indoor air, dietary supplements, consumer products and the environment. NSF International also tests and certifies products to NSF/ANSI and ISO standards. It develops sustainability solutions and training and education programs that cover anything related to the world of food, water and consumer goods sectors. It has collaborated with the World Health Organization since 1997 in water quality and safety, food safety and indoor environments and continues to develop innovative information technology capabilities to meet its goal of creating common grounds between all the stakeholders.

## MEET THE PRESENTER

This article is based on a Webinar originally presented by STLE University on March 18, 2015. "Food Grade Lubricants and Their Regulation" is available at [www.stle.org](http://www.stle.org): \$39 to STLE members, \$59 for all others.

Ashlee Breitner is the business unit manager of the NSF International Consumer Products and Nonfood Compounds programs. She has worked at NSF International for more than seven years and oversees all aspects of NSF's Nonfood Compounds Registration program. She has a background in product testing, consumer products certification and Food Contact Regulatory Compliance.

Now Breitner leads the development of new services, improves existing processes, enhances customer service and represents NSF International at industry events and conferences. She also works closely with NSF-certified companies and industry stakeholders to assure that the NSF programs continue to utilize the most up-to-date regulatory requirements and industry best practices.

You can reach Breitner at [abreitner@nsf.org](mailto:abreitner@nsf.org).



Ashlee Breitner

### LUBRICANTS IN FOOD PROCESSING

As more processes are automated in food production and reliance on machinery increases, there are more pressures on food processors operating with reduced work staff. These companies have higher goals for yields and waste reduction in production facilities while plants and operators are under time pressures with less emphasis on personnel training and education.

There are customer pressures to those sourcing food products around private labeling, contract manufacturing and retailers putting regulatory and additional testing requirements on products. The need to focus on food safety now is growing.

Lubricants used in production processes offer the possibility of cross contamination into food. The growing concern for food-safe lubricants raises questions about whether food safety regulations and standards also apply to food grade lubricants and how food manufacturers meet operational requirements without introducing new chemical hazards.

### THE IMPORTANCE OF RISK MITIGATION

Hazard control in food processing reduces the potential for contamination from both biological agents such as pathogens or spoilage organisms and chemical agents like toxins, carcinogens or mutagens. In order to be effective, hazard control must extend to the following:

- **Processing areas.** Includes receiving, storage, lethality, assembly, packaging, storage and shipping.
- **Infrastructure.** Includes equipment design and construction, surface treatments and coatings and plant steam and water.
- **Maintenance activities.** Includes cleaning, pest control, water treatment and lubrication.

Hazards can be controlled by having effective Hazard Analysis Critical Control Point (HACCP) plans and ensuring they are implemented. They also can be controlled by making sure equipment is designed in a way that is sanitary and doesn't harbor additional bacteria or cleaning agents in areas where they are undesired and by using third-party verified lubricants.

It is important to control against hazards in order to avoid the following:

- Public health crises and foodborne illness outbreaks
- Brand destruction, media attention and consumer litigation
- Product recalls, public notice and product disposition
- Regulatory enforcement, penalties and criminal charges.

Food recalls can affect millions of people depending on where the food is distributed. Repercussions of recalls are significant and can destroy a brand's reputation in the industry.

### INTERNATIONAL REGULATIONS FOR FOOD GRADE INDUSTRIES

The U.S. is heavily regulated and has specific criteria about how to evaluate products with consideration for food safety. Regulation is established by the U.S. Food and Drug Administration (FDA) with NSF International acting as the product certification body.

In the U.S., products must be formulated in accordance with Title 21 Code of Federal Regulations (21CFR) 178.3570. Or the ingredients in the lubricant must be listed as safe in (21CFR) 178.3570 where there is a list of acceptable components including oils, antioxidants, surfactants, etc., along with use limitations. Another option to comply with the regulation could be through an approved contact notification from the FDA.

**European Union (EU).** In the EU the European Food Safety Authority (EFSA) provides advice on food safety risks and publishes scientific opinions on certain compounds (e.g., mineral oils). Today there is no formal EU regulation for lubricants like there is in the U.S. Typically the U.S. compliant requirement is accepted in the EU.

**Canada.** The Canadian Food Inspection Agency (CFIA) enforces that country's regulations. It maintains a list of CFIA-approved chemical compounds but has scaled back the scope of the reviews for the last two years. It used to operate a program similar to the NSF program in the U.S. with similar criteria, but now it applies only

to meat processing. It is uncertain whether CIFA will ramp up the scope or scale it back again in the future.

**China.** The Food Safety authority in China is the Food Hygiene Law of the People's Republic of China. This law ensures food hygiene and protects food products from contamination of harmful substances. It doesn't cover products themselves but instead covers the premises, processing facilities and environments where products are produced.

It doesn't specify hygiene standards for lubricants but says that harmful substances must not be introduced to processing areas. Rather than focus on the hygiene side, it focuses more on potential harmful substances being added into the products that could contaminate the final lubricant.

**Australia.** In the past the Australian Quarantine and Inspection Service (AQIS) operated a program similar to the one in Canada, reviewing and listing products as compliant and mirroring the U.S. criteria for ingredient review. In Australia lubricants with incidental contact are called Lubricants Type A. Two years ago they also suspended their acceptance review program and are no longer adding review products to their list of accepted foods.

**Asia-Pacific.** Several Asia-Pacific countries are strengthening their food safety regulations and expanding laws for food processing. In time more countries in the region may start to focus further on the lubricant sector, but no regulations exist now.

## INTERNATIONAL STANDARD FOR FOOD GRADE LUBRICANTS

To show compliance to the international regulations, there's ISO 21469 Safety of machinery. It helps identify and control potential hazards. It has internationally accepted criteria that doesn't vary from region to region.

ISO 21469 focuses on lubricants with incidental product contact and hygiene requirements—a product certification for lubricants with incidental product contact.

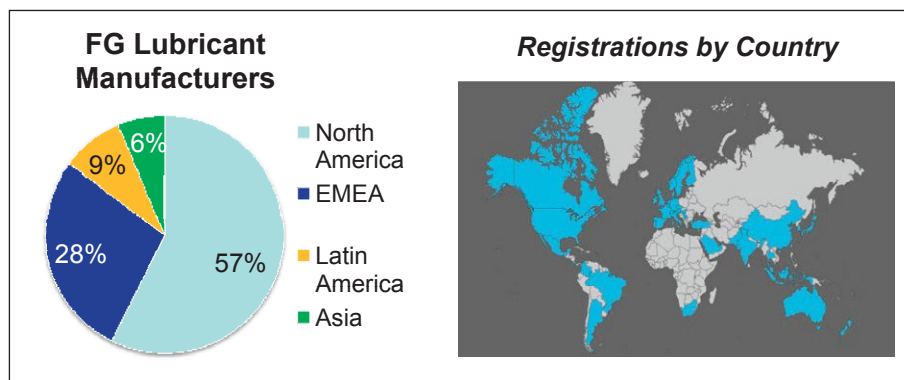


Figure 1 | Breakdown of Global NSF International registrations of all products including lubricants.

## ISO 21469 CERTIFICATION

ISO 21469:2006 is a voluntary product certification standard that is internationally recognized. It specifies hygiene requirements for the formulation, manufacture, use and handling of lubricants. What makes this certification unique is that it does not only apply to lubricants that can come into incidental contact with products and packaging used in the food and beverage sector but also applies beyond food safety to other markets such as:

- Food and beverages
- Cosmetics
- Pharmaceuticals
- Animal feed
- Tobacco.

NSF International operates a product registration program (see Figure 1). It works with clients in 48 countries around the world.

## FORMULATION REVIEW

During the initial certification, each product's formulation is reviewed to verify that all of its ingredients are acceptable against the U.S. criteria. The label is reviewed to confirm that the end use of product is accurate, to confirm that there is traceability on the packaging, to verify correct use of the certification body mark, to confirm that shelf life is indicated and to confirm there are no false claims made on the product, among other things.

## RISK ASSESSMENT

Certification is end-use specific, so both the lubricant manufacturer and

the food processing facility are involved in the risk assessment step. The company going through the certification process identifies potential points of risk within the product and explains what it's doing to mitigate each risk and to prepare for the next step, an onsite audit. Also during certification, lubricant conformity is tested by Fourier transform infrared spectroscopy.

## FACILITY AUDIT

Audits are performed initially for certification and then annually to maintain certification. When auditors visit the production facility where the product is used, they look for many things.

They evaluate potential chemical, physical and biological hazards from a risk assessment standpoint. They check to ensure facilities are using good manufacturing practices and haven't missed any points brought up during the risk assessment. They also check to ensure that what the facility says they are doing to mitigate against the risks is actually happening.

Audits review formulations on file to confirm materials and ingredients are the ones in the facility and being used. They verify correct labeling and packaging are used, that there is a hygienic facility environment and there are raw material testing, release and quarantine procedures in place. Finally, the audit verifies that the facility maintains a standardized quality procedure of at least a minimum ISO 9001.

## ISO 21469 VALUE IN ADOPTION

This standard offers many values to



ISO 21469 has been recognized by governmental authorities around the world. Two examples of early adopters who wrote this into their regulations are:

- The Emirates Authority for Standardization & Metrology, the official federal body in the United Arab Emirates, which recently announced adoption of ISO 21469 as the mandatory requirement for incidental contact lubricants.
- In April 2014 Brazil's National Petroleum Agency (ANP) published *Alguns Artigos da Resolução ANP Nº 22 DE* that now requires ISO 21469 for food grade lubricants produced in or exported into Brazil.

Other governments and countries are expected to follow adoption of ISO 21469 into regulation and continue this growing trend.

ISO 22000 standards certify the food safety management systems of companies in the food production chain, not the food production facility itself. This set of international standards is recognized by the Global Food Safety Initiative and provides assurance that food has been produced, prepared and handled according to the most recognized standards.

Certification is done on the management systems of companies that process or manufacture not only foods but also animal products, perishable vegetable products, products with a long shelf life and other food ingredients like additives, vitamins and bio-cultures. It demonstrates the ability to control food safety hazards from a management systems perspective.

Another option that helps assess and manage hazard risks is registering food grade lubrications with third parties. NSF International offers these types of registration programs as well. During these programs an independent body verifies the safety of lubricants and other chemicals used in food facilities. This type of registration helps manufacturers promote their food grade lubricants and helps end-users identify which lubricants are safe by having a third-party mark on a product.

During registration each and every product's formulation, packaging and labels are reviewed for the particular end-use claimed. There are several requirements that a lubricant product must pass in order to qualify for a third-party mark.

The formulation needs to comply with regulations 21 CFR Section 178.3570 or food contact notification, Generally Recognized as Safe notification or letter of opinion from the FDA or from a qualified legal firm. Each products' labels

Each product receiving a registration mark is given a unique registration number that is completely traceable back to the lubricant manufacturer. Anyone can trace a registered lubricant on an NSF International public Website to check that the product is still registered, is registered for the right end use and what category code it obtained. Registration is not a one-shot event and must be maintained for each end-use and category code.

There are many categories for lubricants. But the most prominent are H1, H2, H3, HX-1 and HT-1. The main category for lubricants is H1, which is generally referred to as food grade lubricants for incidental contact. These lubricants are not intended for direct, intentional contact with food.

HX-1 is a category for the ingredients that goes into forming an H1 lubricant. HX-1 is not for lubricants themselves but for prescreened components and additives meeting the requirements for H1 lubricants. This category helps formulators by increasing the likelihood of acceptance. There are more than 470 registered HX-1 ingredients by more than 80 companies.

H2 is the category for noncontact lubricants, those that should have absolutely no contact with food. These lubricants

JANUARY 2016 • 29

are intended to be used somewhere else in a food production facility but not on the line that processes food. The registration process performs a general overview to make sure there are no carcinogens in the product and other general health and safety areas. When manufacturers register these lubricants, food manufacturers have added reassurance that a third party has reviewed them.

HT-1 is used for heat transfer fluids in primary and secondary heating and cooling systems in food processing facilities. H3 is used for soluble oils that are used to treat hooks, trolleys and other similar equipment that may contact food or edible products.

## NEXT STEPS FOR LUBRICANT MANUFACTURERS

Risk mitigation is important for food processors because not only are contamination incidents costly, recalls and negative publicity can destroy brands. Even if a one-time contamination occurs, producers will be subject to additional scrutiny. The same goes for those producing unsafe lubricants, whose brand reputation also could be on the line.

While some countries such as the U.S. and Canada regulate lubricants outright, others such as China are not specific but imply compliance. Many countries don't have any regulations regarding food safety at all for lubricants.

But voluntary standards and third-party registration programs exist and continue to grow. These increasingly are seen as ways to mitigate risks while complying with regulations that do exist.

Breitner advises that the best way to help ensure brand recognition and grow lubricant products is to start the compliance process now before exposure to risk. She advises people to mitigate risks by learning about standards, certification and registration programs early. **TLT**

*Debbie Sniderman is an engineer and CEO of VI Ventures, LLC, an engineering consulting company. You can reach her at [info@vivllc.com](mailto:info@vivllc.com).*

## FOR MORE INFORMATION

NSF International: [www.nsf.org](http://www.nsf.org)

Title 21 Code of Federal Regulations (21CFR) 178.3570: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=178.3570](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=178.3570)

ISO 21469 Certified Lubricant Search: [http://info.NSF.org/Certified/iso\\_21469/](http://info.NSF.org/Certified/iso_21469/)

The ISO 21469 Standard: [www.iso.org/iso/home/store/catalogue\\_tc/catalogue\\_detail.htm?csnumber=35884](http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35884)

Performance and service that are

# LEADING EDGE

People and specialty products  
you can count on.

- SpectraSyn Elite™ mPAO Polyalphaolefin Base Oils Group IV
- SpectraSyn Plus™ Base Oils Group IV
- SpectraSyn™ Polyalphaolefin Base Oils Group IV
- Esterex™ Esters Group V

- Synesstic™ Alkylated Naphthalene Group V
- Ultra-S™ Base Oils Group III
- Pure Performance® Base Oils Group II
- ConoPure® Process Oils



Global Sales and Service

7010 Mykawa | Houston, Texas 77033 | 800.228.3848 | [www.jamdistributing.com](http://www.jamdistributing.com)

Esterex, SpectraSyn, SpectraSyn Ultra and Synesstic are trademarks of Exxon Mobil Corporation. Ultra-S is a trademark of S-Oil Corp. and Pure Performance and ConoPure are registered by Phillips 66 Company.

# J.A.M.

**SPECIALTY PRODUCTS**