



INTERNATIONAL REGULATIONS FOR *FOOD GRADE LUBRICANTS*

While awareness of food grade lubricants has grown significantly in the last ten years, according to Ashlee Breitner of NSF International, much confusion remains surrounding food safety standards and regulations that apply to these specialty lubricants and greases. “In many countries, it is unclear if government imposed food safety laws extend to food grade lubricants and other processing compounds,” Breitner said in a presentation at the 19th International Tribology Colloquium at the Technische Akademie Esslingen, Germany, in January.

“Few governments directly regulate the use of food grade or incidental contact lubricants,” she said, “and most lubricant formulators rely on criteria established in Title 21 of the U.S. Code of Federal Regulations for guidance.”

Along with good risk management practices, lubricant suppliers must have a clear understanding of the relevant standards to meet the demands of the global food industry and to protect public health and safety.

Breitner, based in Ann Arbor, Michigan, United States, reviewed international regulations for the design, formulation and manufacture of food grade lubricants and their components, including base oils and performance enhancing additives. She also covered voluntary standards used around the world.

The Concern

“Food grade lubricants are essential to safe facility operations,” Breitner said. “The custom configuration and scale of equipment in food plants combined with challenging environmental conditions (steam, condensate, heat and organic matter) means lubricants and greases with custom performance characteristics often must be used.”

The challenge of meeting operational requirements without introducing chemical hazards that must be managed as critical control points can be met by using properly evaluated food grade lubricants. “Today’s food processors are proactively sourcing food grade lubricants as a logical alternative to traditional industrial products,” said Breitner. “The use of food grade lubricants and greases, along with a properly

implemented HACCP [hazard analysis and critical control points] plan, provides an effective way to manage chemical risks.”

Food grade lubricants are formulated to be innocuous with respect to taste and odor, and they do not pose a significant health risk should contamination occur, Breitner continued.

Europe & North America

Breitner said, “There are no [pan-]European regulations for the formulation of incidental contact lubricants used in food processing facilities.” Other countries, however, have been more active in regulating food contact lubricants.

For example, the Canadian Food Inspection Agency enforces the policies and standards set by Health Canada that govern the safety and nutritional quality of food sold in Canada. “The CFIA also helps implement HACCP systems in all federally registered food establishments,” Breitner said. “The agency requires the use of approved chemical compounds as a prerequisite for the application of HACCP programs by these manufacturers.”

Canada typically accepts the formulary criteria established in U.S. Title 21 CFR Section 178.3570 for incidental contact lubricants. Products accepted by CFIA, including food grade lubricants, can be found on the Internet.

“In the U.S., food grade lubricants are categorized as incidental food contact lubricants according to the U.S. Food and Drug Administration,” Breitner noted. “The FDA specifies that incidental food contact lubricants must be formulated in ac-

cordance with a number of criteria.”

The first option is Title 21 CFR Section 178.3570, which lists acceptable lubricant components, including oils, antioxidants, surfactants and other adjuvants, along with use limitations for each component. The second possible criterion is that the lubricant be a substance generally recognized as safe (GRAS) as listed in 21 CFR Parts 182 and 184. Third, the substance can be used in accordance with the provisions of a prior FDA sanction or approval. Finally, the lubricant must be approved through the FDA Food Contact Notification approval process. Components with novel chemistries, such as performance enhancing additives, can obtain authorization for use in incidental contact lubricants via the notification process.

Breitner explained, “The USDA used to review and authorize lubricants acceptable for use in food processing and handling.” These lubricants were evaluated against the requirements of 21 CFR. “In 1999, NSF International, a not-for-profit, public health organization took over the responsibility of evaluating food grade lubricants and other food processing substances,” she added.

Working with the USDA, NSF captured all previous review requirements and launched a third-party registration and listing program for food grade lubricants. Lubricants acceptable for incidental food contact are identified or categorized as H1 lubricants.

In January 2011, the U.S. passed the FDA Food Safety Modernization Act, which reflects a significant change in food safety laws. This legislation mandates preventive

measures by growers, processors and distributors, provides for increased inspections and gives the FDA greater regulatory authority.

“Areas of focus are hazard analysis, validation and ensuring verification systems are in place,” Breitner said. “This law will have far-reaching implications for the global food supply chain.”

In addition to stricter measures for U.S. processors, the law establishes new requirements for labeling, import, supplier qualification programs and mandatory recall authority. The law also expands the jurisdiction of the FDA and increases penalties for companies that distribute products that are harmful or unsafe.

Australia & Asia

“In Australia,” Breitner said, “the Australian Quarantine and Inspection Service requires the use

With the emergence of international food safety standards like ISO 21469 and 22000, the food industry has tools to proactively identify, analyze and manage risks.

of approved chemical compounds, including food grade lubricants, in registered export red meat establishments.” According to AQIS guidelines, listed substances, in addition to GRAS substances, are acceptable for use in formulating lubricants. Substances listed in the guidelines are taken from 21 CFR 177.1550, 178.3400, 178.3570, 178.3700 and 178.3740(b). Breitner added, “Under AQIS, lubricants with incidental food contact are categorized as Lubricants Type A.”

She explained that India and China are strengthening food safety regulations and expanding laws

to include various aspects of food manufacture and packaging, including processing compounds that could potentially contact food. China’s food hygiene law sets the standards and requirements for ensuring food hygiene and protecting food products from contamination with harmful substances.

The law applies to all parties engaging in food production or marketing food products within China. It applies to all foods and food additives as well as containers, packaging, utensils and equipment used for food, detergents and disinfectants. In addition, it covers the premises, facilities and environment associated with food production or marketing.

“While the law does not specifically call for hygiene standards for food grade lubricants,” Breitner said, “it clearly states that harmful substances must not be introduced into processing environments. Today, demand for food grade lubricants is increasing in China, driven largely by rising awareness within the food processing community and the desire to export food products to Europe and North America.”

ISO Standards

The International Standards Organization has issued two standards to help ensure food safety around the world. “With the emergence of international food safety standards like ISO 21469 and 22000,” said Breitner, “the food industry has new tools to proactively identify, analyze and manage risks.”

ISO 22000 is a certification system for food manufacturing recognized

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Email: DzholdasovaKB@lukoil.com

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by the Global Food Safety Initiative. "ISO 22000 was developed to certify food safety systems of companies in the food chain that process or manufacture animal products, perishable vegetable products, products with a long shelf life and other food ingredients like additives, vitamins and biocultures," Breitner explained.

ISO 22000 enables food suppliers to assure customers that food has been produced, prepared and handled according to the most recognized standards. It also demonstrates a commitment to quality processes and continual improvement, and enables access to top retailers. ISO 22000 sets out requirements for a food safety management system and determines what an organization needs to do to demonstrate its ability to control food safety hazards and

ensure that food is safe.

ISO also developed a voluntary standard for lubricants in 2006. "ISO 21469 specifies the hygiene requirements for the formulation, manufacture and use of lubricants that may come into contact with products during manufacturing," said Breitner. The standard applies beyond food applications and includes lubricants used for processing products such as cosmetics, pharmaceuticals and animal feed, where hygiene is of particular concern.

She explained that "ISO 21469 requires lubricant manufacturers to develop a risk mitigation strategy and to consider the chemical, physical and biological hazards of lubricant use." Certification to ISO 21469 also requires that lubricant manufacturers complete a risk assessment addressing potential sources

of lubricant contamination during production.

International regulatory agencies are already responding to the new ISO standard. The United Arab Emirates' Standardization & Meteorology Authority adopted ISO 21469 as the mandatory requirement for incidental contact lubricants earlier this year.

Standards like ISO 21469 and 22000 set requirements for organizations in the food chain to demonstrate their ability to identify and control potential hazards. According to Breitner, "The most effective way for food facilities to manage risks in their processes and supply chain is to implement an effective HACCP plan." HACCP identifies where potential contamination can occur and manages and monitors these areas, ensuring the process is in control

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and that the safest product possible is being produced. "HACCP-based food safety programs place the responsibility on food processors to prevent rather than catch potential hazards," she said.

HACCP is globally recognized by food manufacturers, food safety agencies including the World Health Organization, the Food and Agricultural Organization of the United Nations and many governments as the predominant science-based method to ensure hygienic food production. The ultimate objective of these standards is to ensure that food is safe at the time of consumption.

NSF Registration

NSF's registration program is an internationally recognized resource for evaluating, registering and listing food grade lubricants. To register

a lubricant with NSF, the formulation and the product label must be reviewed against the requirements of 21 CFR.

The lubricant must be formulated using ingredients listed in 21 CFR Section 178.3570, which also references GRAS substances. In addition to being 21 CFR compliant, an ingredient can be acceptable for use in a food grade (or H1) lubricant if it has a:

- Food contact notification,
- Threshold of regulation exemption,
- GRAS notification, where the indicated use is as an ingredient in a lubricant with incidental food contact, or
- Letter of opinion from the FDA or qualified legal firm submitted to NSF for review.

"In addition to formulary require-

ments, labeling must be accurate with no misleading claims and include appropriate end-use instructions," Breitner cautioned. "Product labels must also be traceable to the registered company and bear the NSF Registration Mark, including the H1 category code and unique product registration number."

Since its inception, the NSF registration program has been supported by lubricant manufacturers, regulatory inspection bodies and end-users. "Global interest in the registration program continues to grow," Breitner said. "Currently, over 700 H1 lubricant manufacturers are listed worldwide, and 7,700 products are registered in the NSF online listing."

In 2008, NSF launched a certification program for lubricants that meet the requirements of ISO 21469.

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Requirements differ from H1 registration mainly by adding risk assessment, production facility audits and annual product testing to the formulation and label review.

“For certification, the risk assessment is conducted to ensure that the manufacturer has identified and evaluated relevant hazards associated with the manufacture and use of the lubricant,” Breitner said. NSF audits production facilities to confirm that requirements are met and the manufacturer follows good manufacturing practices.

Finished lubricants are tested annually to verify the integrity of the product composition. The certification process is streamlined for products that are currently H1 registered because H1 formulary requirements also satisfy ISO 21469.

NSF also offers an ingredient category designated HX-1 for components and additives that have been prescreened and determined to meet the requirements for finished H1 lubricants.

“Using pre-approved HX-1 ingredients helps formulators reduce the uncertainty of ingredient suitability,” Breitner added. The NSF registration letter for each ingredient specifies its use limitations. “Currently, over 470 registered HX-1 ingredients supplied by more than 80 companies are listed on the NSF

website.”

Additional registration categories exist for lubricants with special applications that may come into contact with food during use. The HT-1 category applies to heat transfer fluids used in primary and secondary heating and cooling systems in food processing facilities. To meet NSF requirements, these fluids must be formulated with ingredients that comply with 21 CFR Section 178.3570 or 21 CFR Part 172.

Breitner concluded, “The H3 category is for soluble oils used to treat hooks, trolleys and similar equipment that may contact food or edible products.” Ingredients may consist of edible oils complying with 21 CFR Section 172.860, mineral oils complying with Section 172.878, or GRAS substances complying with 21 CFR Parts 182 or 184. □

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