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Food-grade Lubricants and Their Place in the HACCP Program

For a food, beverage, cosmetic or pharmaceutical company, or any other firm that manufactures products that will be directly consumed or used by people, processes must be highly scrutinized for cleanliness, contamination, sanitation and quality. For this reason, such companies have a particularly difficult task when it comes to lubrication – not just the task of lubricating correctly, but in determining which lubricant to use and where.

Food-grade Lube Performance

As with any lubricant, food-grade lubricants must meet the needs of proper lubrication. That means a lubricant must provide the metal-to-metal surface separations, contain performance properties like anti-wear (AW) and rust and oxidation inhibitors (RO), and employ any other performance properties and base oil classifications that the application requires. In addition to these typical needs, food-grade lubricants must also stand up to a wide range of contamination issues. For example, in a meat processing plant, equipment is subjected to large amounts of steam and high-pressure caustic water cleaning. Lubricants in these types of facilities must withstand the probability of water washout as well as help in controlling rust formation within bearings and gearboxes.

Another requirement of food-grade lubricants is their need to withstand contaminants (like sugars, dust, chemicals, etc.) that occur as a direct result of the manufacturing process.

While most facilities requiring food-grade lubricants are conscientious of the operation and condition of their equipment, lubricant leakage does happen. Leaks can cause a severe amount of downtime, ranging from containing the leak to documentation to clean-up. Food-grade lubes are made and required to be tasteless, odorless and physiologically inert. These properties greatly reduce the hazard level that lubricant exposure has on the product.

Food-grade lubricants also should be able to withstand and deter the growth of fungi, bacteria and other pathogens. The formation of bacteria is very likely in the wet environments of meat processing plants. Bacterial contamination is another critical factor to consider and control in the food and beverage industry.

Lubricant Classifications

Historically, the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) were responsible for compiling, determining, and writing the standards and classifications for food-grade lubricants. In February 1998, the USDA changed the way manufacturers assessed and organized the usage of food-grade lubricants. It allowed manufacturers to assess each point in production and determine its critical limit for risk of contamination, which warranted the decision to use food-grade or non-food-grade lubricants. This led the way for development of the Hazard Analysis and Critical Control Points (HACCP) program.

The primary current food-grade lubricant classifications are:

- **H1:** Lubricants used in food processing environments where there is the possibility of incidental food contact.
- **H2:** Non-food-grade lubricants used on equipment and machine parts in locations where there is no possibility of contact.
- **H3:** Food-grade lubricants, typically edible oils, used to prevent rust on hooks, trolleys and similar equipment.

In order for food-grade lubricants to be classified in one of these three categories, they must comply with certain codes within the FDA's Title 21. These codes dictate and approve what ingredients can be used in a particular food-grade lubricant that may incur incidental contact. Samples of the FDA Title 21 codes are:

- **21.CFR 178.3570:** Outlines allowed ingredients for the manufacture of H1 lubricants
- **21.CFR 178.3620:** White mineral oil as a component of non-food articles intended for use in contact with food
- **21.CFR 172.878:** USP mineral oil for direct contact with food
- **21.CFR 172.882:** Synthetic iso-paraffinic hydrocarbons
- **21.CFR 182:** Substances generally recognized as safe

Even though H1-classified food-grade lubricants are made with the ideology of incidental contact with food, the allowable lubricant contamination constituted by the FDA is 10 parts per million.

Food Contamination Hazards and Control

With an ongoing battle between production, quality and food safety, most manufacturing facilities have implemented some type of identification process for food-grade lubricant usage, but it usually falls short of being comprehensive.

In the 1960s, the U.S. National Aeronautics and Space Administration (NASA) developed a strategic program that adopted traditional inspection techniques with a science-based food safety system. The program uses a proactive and preventive method for identifying risk by inspecting and examining any production point, or "critical control point", for food contamination risk. This is known as the Hazard Analysis and Critical Control Point (HACCP) program. HACCP can be implemented through the entire manufacturing process, production to packaging.

HACCP has been a success in monitoring and controlling food and beverage industry contamination risk, and is now being used in cosmetic and pharmaceutical industries. In the United States, HACCP is in compliance with and regulated by 21.CFR 120/123. Seven principles help guide companies to develop and implement a successful HACCP program. They are:

Principle 1: Conduct a hazard analysis. Plants determine the food safety hazards and identify the preventive measures that the plant can apply to control these hazards.

Principle 2: Identify critical control points. A critical control point (CCP) is a point, step or procedure in a food process at which control can be applied. As a result, a food safety hazard can be prevented, eliminated or reduced to an acceptable level. A food safety hazard is any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

Principle 3: Establish critical limits for each critical control point. A critical limit is the maximum or minimum value to which a physical, biological or chemical hazard must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level.

Principle 4: Establish CCP monitoring requirements. Monitoring activities are necessary to ensure that the process is under control at each CCP. The USDA's Food Safety and Inspection Service (FSIS) requires that each monitoring procedure and its frequency be listed in the HACCP plan.

Principle 5: Establish corrective actions. These actions are taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product enters commerce that is injurious to health or otherwise adulterated as a result of the deviation.

Principle 6: Establish recordkeeping procedures. The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of CCPs, critical limits, verification activities and the handling of processing deviations.

Principle 7: Establish procedures for ensuring the HACCP system is working as intended. Validation ensures that the plans do what they were designed to do; that is, they are successful in ensuring the production of safe product. Plants are required to validate their own HACCP plans. The FSIS does not approve HACCP plans in advance but reviews them for conformance with the final rule.

Verification ensures the HACCP plan is adequate (working as intended). Verification procedures may include activities such as review of HACCP plans, CCP records, critical limits, and microbial sampling and analysis. The FSIS requires that the HACCP plan include verification tasks to be performed by plant personnel. FSIS inspectors also perform verification tasks. Both FSIS and industry undertake microbial testing as one of several verification activities. Validation is the process of finding evidence for the accuracy of the HACCP system.

The seven HACCP principles are included in the ISO 22000 standard, an industrial-specific risk management system for any type of food processing and marketing. It can be closely incorporated with a quality management system.

How to Gain HACCP Success

To create a successful HACCP program, consider all other quality- and manufacturing-related tasks. A proper and successful lube program should be at the top of the list. To successfully identify critical points, consider the manufacturing environment and process and all lubrication requirements of the equipment. Manufacturing processes expose food and beverage products to equipment that requires proper lubrication to operate at optimum performance and reliability. This exposure increases the likelihood of food contamination due to lubricant leakage or contact. To help combat such contamination, employ successful relubrication regimes and equipment modifications for contamination control. These are two fundamental aspects of a successful lube program.

Proper relubrication for greasing and oil top-ups help control the amount of lubricant exposure to which the manufacturing process is subjected. Many times, food processing plants regrease too frequently due to the severe washdown environment. Overgreasing increases the risk of lubricant contact with the food or beverage product. Oil top-ups provide less exposure to the food or beverage product by means of equipment location. Most oil-lubricated equipment is located farther away from critical production areas, with the exception of overhead conveyors and agitators. For these two applications, sensitive top-ups should be a top priority to avoid spills that cause timely loss of production. To assist in avoiding spills, top up oil-lubricated components using high-quality containers.

Equipment modifications are another important factor in creating and implementing a successful lube program. These modifications range from breathers to quick couplers for offline filtration and top-ups. By reducing the amount of outside contamination ingression, water or dirt to which a piece of equipment is subjected, it greatly reduces the need for more frequent relubrication. This lowers the risk associated to a particular CCP for lubricant contamination.

Once you have developed your HACCP and lubrication programs, maintaining their consistency and effectiveness should be an ongoing process. Constantly refine and improve them based on past experiences of what worked or what did not. An example could be lubricant cross-contamination. This is a big issue, especially with food-grade lubricants, as many H1-classified lubes are not compatible with H2 and H3 lubes simply due to different performance properties. To help avoid cross-contamination, utilize the following:

Identification: All lubricants from the storage area to the lube technician's cart to the application should be well identified using a standard identification system. Complete this by implementing colored labels on each lubricant container (bulk, top-up and grease gun). These match the same colored label on the lube point.

Consolidation: Consolidate the quantity and types of lubricant you keep, but do not sacrifice the right product for the application based on consolidation. Doing so may cause premature equipment failure.

It Takes Time and Resources

You can see just how difficult it can be to deal with the restrictions that food, beverage, pharmaceutical and cosmetic companies face when dealing with quality and cleanliness control and implementing proper lubrication techniques. With the limited selection of food-grade lubricants, it is critical to take the time to determine the correct product per application.

The implementation of any program (HACCP or strictly lubrication) takes time, resources and confidence to complete successfully. Many times, facilities look for an immediate return on these types of programs and investments. While that is not wrong to expect, it just does not happen immediately. These types of programs take time to develop and reach their full potential and must keep evolving with the demands of the facility. Luckily, programs can evolve and morph as many times as required. ML

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