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Guidelines for segregation within production

Food producers today hear the words ‘recall’ and ‘risk mitigation’ on a regular basis – they are typical focuses for the quality teams that are responsible for delivering a safe and effective product. In recent years, there has been a shift in government regulations and inspections pertaining to food safety from control strategies to a strategy with a greater focus on risk management. Potential sources of food contamination can stem from anything from environmental conditions to food additive ingredients to lubricants or cleaners used in or on food processing machinery.

When it comes to chemical compounds used in food processing whether it's a lubricant or a cleaner most of the attention has been focused on the ingredients used to formulate these products. The third party independent registration body, NSF International, has continued the responsibility of reviewing formulations and product labels and publically listing approved nonfood compounds and ingredients, from the U.S. Department of Agriculture (USDA). This registration program places the main emphasis for food safety in lubricants on the formulary ingredients within the final products.

Though the formulation is an extremely crucial component, the production process of these compounds and application of the compounds on the equipment are just as critical. Recently the National Lubricating and Grease Institute published an updated version of their Lubricating Grease Guide to include a modernised version of the *Guidelines for the Manufacture and Application of Food Grade Greases*. This document is to provide a basis for the design and operation of the

processing facility for food grade greases. These are guidelines which may help to prevent contamination of food grade grease during the manufacturing process of the actual grease. The process overviewed in this document includes material handling, processing equipment, the processing environment, and packaging. The overall objective of these guidelines is to mitigate the potential for contamination of food grade greases prior to their use in food processing equipment and facilities. Though these guidelines were written for the intention of food grade grease application and production the core logic behind them can be applied to all compounds used for food production including cleaners, coatings, heat transfer fluids, and even laundry products.

Manufacture of food grade grease

Food grade grease (H1) is a grease product used on food processing equipment as a protective anti-rust film, as release agents on gaskets or seals of tank closures, and/or as lubricants for machine parts and



equipment. These products, more commonly known in the industry as H1 lubricants, are not designed or approved for direct food contact; rather they are meant for incidental contact only. The U.S. Food and Drug Administration (FDA) defines that incidental contact should be no more than 10ppm.

Food grade grease approved for use as an H1 lubricant can be used in a food processing setting, and can be used 'above the line' as well as 'below the line' wherever there is a potential chance of food contact. Another grease category, H2, may find its way into a food manufacturing facility but it is often stated as being suitable for use 'below the line', that is the below the food processing line where there is a zero chance of food contact. H2 products are not acceptable for any contact with food stuff.

According to the NLGI's '*Guidelines for the Manufacture and Application of Food Grade Greases*': "Food grade grease (H1) may see conditions every bit as extreme as or worse than industrial grease. Temperatures may range from -80°C (-112°F) to 200°C (392°F), contact with water and cleaning fluids is routine, contact with acidic fluids is common, high loads, wear, and high shear are also normal. Grease is made up of three distinct components – a thickener, a lubricating fluid and one or more performance enhancing additive. For food machinery grease, the range of acceptable choices for each is less than for industrial grease. Suppliers of the components used in the manufacture of these products should be consulted to ensure that their raw materials, fluids, and additives are acceptable for use, are handled properly, and are free of any undesirable contaminants. Consult the NSF website at <http://info.nsf.org/USDA/psnclistings.asp> to identify food grade lubricant and grease components have been pre-registered for use."

Materials

The overriding consideration with the manufacturing process of food grade grease or any other compound used in food production and that is approved for incidental contact, is segregation throughout the

production process. This concept would include the segregation of materials and the segregation of processes. The key factor when considering the segregation is the necessary mitigation of the risk of contamination from 'foreign' materials. Foreign material contamination can occur as result of inadvertent raw material contamination, residual product contamination, or exposure of 'foreign' materials within the manufacturing environment. Ideally, the better the segregation efforts, the lower the risk of contamination that is possible.

The following are critical elements within the manufacturing process that need to consider segregation, as stated in the *Guidelines for the Manufacture and Application of Food Grade Greases*:

"Packaged raw materials: Packaged raw materials have a degree of segregation by virtue of their containers. However, designated and/or dedicated storage areas for these raw materials could reduce the risk of selecting the wrong raw material for use in food grade product. Furthermore, partially filled containers could also be less subject to environmental contamination if the packaged raw materials are re-sealed during storage and staged in a dedicated area." Cleaning of stored product containers within the designated areas before opening the packaged product can help to eliminate the risk associated with potential contamination.

"Bulk raw materials: Bulk raw materials, especially base oils, are likely to be used in a multitude of products, including food grade greases. With bulk raw materials, it is critical to assure segregation of non-approved raw materials from the food grade grease production units, including transfer and unloading lines, and storage tanks."

Processing

A major element of the International Standard ISO 21469, Safety of

FOOD GRADE LUBRICANTS

SUPPLEMENT

Machinery-Lubricants with Incidental Product Contact-Hygiene Requirements, is the product and production facility risk assessment. This Risk Assessment looks at all aspects of potential risks associated with the production of these products including a company's current practices of segregation. This risk assessment evaluates each stage of the production process from blending to packaging and its potential risk factors. In addition it assesses the certified product production process in relation to non-food grade product production within the same facility to identify potential risks and put measures in place to mitigate those risks. Key aspects evaluated for segregation within the manufacturing process include: Compounding, Blending, and Processing.

The *Guidelines for the Manufacture and Application of Food Grade Greases* states:

“Equipment: It is always recommended to use dedicated kettles, lines and other equipment for making food grade greases to avoid contamination and costly flushing or clean out of these units. Polished stainless steel vessels or sanitary piping systems are not required for the manufacture of food grade grease as it is for processing food products. However, if flushing or cleaning between batches of food grade grease is desired to control contamination...at a minimum, the processing and transfer systems for food grade grease should be totally separate from the rest of the grease processing systems.

“Control: Control has two primary components when considering segregation within the food grade grease manufacturing process. The first is actual control of flow streams, as mentioned above, to prevent

contamination by non-approved raw materials. The second is automated or semi-automated documentation. Each of these components can be easily addressed through the use of PLC (Programmable Logic Controller) systems. Manual systems and procedures can support the segregation needed within the process, but PLC control can raise the level of reliability.”

Additional factors

In addition to the raw material storage and processing of the lubricants, there are additional risk factors still housed within the manufacturer's control that should be evaluated for the possibility of segregation. These factors include the environment in which they are housed, the filling and packaging of the final or bulk product and the handling and transportation of the product including transfer to clients, shipping and repackaging of final product.

“Environmental Conditions/Exposure: One of the more difficult aspects of assuring no contamination of food grade grease during the manufacturing process is the potential for contamination from materials around the process, both airborne and incidental contact. Clean air and good housekeeping are key to assuring no contamination results from the manufacturing environment. Since most grease manufacturing facilities handle solids in one form or another, tramp dust can escape to adjacent work areas and find a way into the other kettles in the area. At some point, this may be a concern to certifying agencies and, therefore, should be considered before this becomes an issue. Ultimately, a separate, environmentally-controlled room would be desirable for containing the food grade grease manufacturing

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process. Such a room would be cleanable, less susceptible to contamination from the surrounding grease processes, and present a positive image to customers/clients as well as any certifying agency representatives.

“Filling and packaging systems: Since filling and packaging equipment are very difficult to fully clean after each use, food grade greases should be filled using dedicated equipment. . . Like the manufacturing process, the filling and packaging operations would be best served if located within an environmentally controlled area. Once packaged and sealed the food grade greases can be handled and stored within the common facility,” as stated in the *Guidelines for the Manufacture and Application of Food Grade Greases*.

Handling/transportation: Quality control measures are necessary to be in place to ensure the correct products, acceptable for use as food grade are transported to clients as requested and that non-food grade products do not accidentally get sent in the order. Separate storage areas for food grade vs. non-food grade products for the loading and distribution of orders could assist with the quality measures to ensure appropriate product delivery.

Summary

Implementation detailing segregated process, equipment, storage and procedures within a production facility is not something that is easy to accomplish after the facility is designed and built though it can be accomplished with diligent processes. With a planning and focus on each of the key aspects of the process creating procedures that

adequately use segregation is achievable and will eliminate a significantly harmful risk associated with product and brand protection. Ideally starting to consider these types of segregation concerns in the design of a new facility would be best for the successful implementation of the quality measures necessary. A successful Risk Assessment for the ISO 21469 certification process aids in the evaluation of these measures, the risk associated with not having the measures in place and the steps to continue to be taken to mitigate those potential risks.

As continued attention is given to the potential impact of lubricants and all nonfood compounds used in a food production facility within the food safety world, a properly segregated, controlled, and documented manufacturing process will aid in assuring quality product is produced each and every time it is manufactured and for each and every customer it is delivered to.

About the Author

Ashlee Breitner is Business Unit Manager of the NSF Nonfood Compounds Registration program. Ashlee has worked at NSF International for five years serving in positions with NSF International, including Group Leader for the NSF Consumer Products program. Her expertise in the NSF certification process enriches the Nonfood Compounds Registration program and continues NSF’s mission to deliver a program that provides product manufacturers, food producers and regulatory/inspector groups with a proven method to determine product acceptability. Ashlee oversees all aspects of NSF’s Nonfood Compounds Registration program. She leads the Nonfood Compounds team in developing new service offerings, improving existing processes, enhancing their customer service skills and representing NSF International at industry events and conferences. Ashlee also works closely with NSF Registered companies and regulators, assuring that the NSF Nonfood Compounds Registration program continues to utilize the most up-to-date regulatory requirements and industry best practices.



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