The History and Future of Food Processing Lubricants

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Introduction#

Machinery touches most of the food we consume today. From picking to packaging, industrial equipment is used to handle and process food. This machinery must be lubricated, meaning there is a possibility of interaction between the lubricant and the food itself. This paper discusses the regulations around this special class of lubricants which must perform all of the normal functions of a lubricant with the added requirement that it will not affect the quality or safety of the food being processed. Using the historical background to provide a context, we see how the regulations developed and also discuss attempts by the industry toward global harmonization.

1. Trust

Is anything more universal in the human experience than our relationship with food? Certainly everyone eats, but the role of food goes far beyond mere sustenance. People connect emotionally with food which explains why people spend so much time and energy on the eating experience. However, people will not eat food they do not trust. We may forgive a worm in an apple or a stale piece of bread, but one bad experience could be enough to end our taste for a certain kind of food forever. And we will delightfully retell the story of the experience to everyone we know. Dogs may return to the chocolate that made them sick, but people have a long memory and follow the adage “once burned, twice shy”. It is easier to lose someone’s trust than it is to gain it.

Much of the value of a brand is in the implied trust consumers have in products that carry the brand label. Companies have a vested interest in food quality because brands that market untrustworthy foods will not stay in business for long. Foodborne illness can quickly become a headline story and can break the trust in companies and countries. Of course, when a problem does happen, people expect government to take action.

2. Defining Acceptable Food Practices

Most people have faith that someone is keeping watch on the food supply and any product on the grocery shelf is safe to eat. In fact, a combination of government, business and societal oversight makes it extremely unlikely that an unsafe food will reach the consumer. Still, few people actually know how this system works or realize that it covers ancillary items such as lubricants.

Religious standards

Major religions, governments, private organizations, and the United Nations have all established standards for the food we eat. In the days of small farms and local food, it was easy to know the expectations, but globalization can lead to many overlapping and confusing regulations.

Food standards have existed since the earliest days of civilization and are written into the texts of major religions. While the texts themselves are unchanging, authorities must interpret the guidelines in the context of the modern world of industrial food processing. The Malaysian Department of Standards recently published Malaysian Standard MS 1500:2009 to document the Halal rules[i].

Today, many foods carry Kosher and Halal certifications which show that the food was prepared according to the appropriate guidelines and meets the standards expected by religious consumers. There are strict regulations that prohibit the foodstuffs from coming in contact with forbidden materials. Lubricant manufacturers can obtain Kosher and Halal certifications to verify that their products do not contain forbidden ingredients. Therefore, the lubricant can be used on equipment which will prepare Kosher and/or Halal food. There are several organizations that certify lubricants and other process ingredients, and they often conduct audits to ensure compliance.

Codex Alimentarius

The World Health Organization (WHO) and Food and Agriculture Organisation of the United Nations (FAO) created the Codex Alimentarius Commission in 1963 to "develop harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations."[ii] This is a truly global standard as 99% of the world's population live in countries accepting the Codex Alimentarius. Additives are covered under The Codex General Standard for Food Additives[iii] (GFSA Codex Standard 192-1995). This document is periodically reviewed and revised under the supervision of the Codex Alimentarius Commission. The current revision (2015) is 396 pages long and provides extensive guidance on the acceptable uses of edible products that are determined to be safe by the joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. Application to the Lubricants Industry

Industrial scale food production is a relatively new and rapidly growing business. Today, approximately 75% of the average diet consists of processed foods. The equipment must be lubricated and often there are opportunities for the lubricant to become part of the food itself. Processed food commonly travels across borders, so global standards are essential.

Edible lubricants

Many food grade lubricants are based on fully edible products. The Codex Alimentarius document goes to great lengths to describe edible products. Unsurprisingly, vegetable oils and tallow, lard and similar

products are edible and can also act as lubricants. Perhaps fewer people realize that petroleum derived products such as mineral oil and microcrystalline wax are also acceptable additives for some types of food. Even talc, iron oxide, stannous chloride, ferrocyanides and other inorganic chemicals are considered perfectly safe food additives[iv].

It would be easy to assume that any product which is an acceptable food additive would be allowed for a non-food lubricant. However, that isn't necessarily true. Conversely, there are many substances which are acceptable as incidental contact food lubricants that are not considered food additives.

Industry learned long ago that edible oils have significant deficiencies that limit their usefulness as lubricant base oils. Edible oils tend to solidify at low temperatures, smoke when heated and polymerize when kept hot. Industrial machinery often demands higher performance and the lubricants of choice are based on refined petroleum and synthetic chemistries that can withstand the severe conditions. Modern food processing plants use the same types of equipment used in other industries and can operate under similar severe conditions. Therefore, the food industry relies on high performance lubricants which are preferred over edible oils. They must perform as industrial lubricants with the added requirement that they are non-toxic and harmless in case of incidental food contact.

Incidental contact (non-food) lubricants

This paper is intended for producers and users of industrial lubricants, so the focus will be on applications requiring non-food products where the lubricant may have incidental contact but should not intentionally become part of the food supply.

A truly rigorous food safety investigation would determine the quantity of lubricant which could possibly be incorporated in the food and ensure that there are no negative effects in the safety and quality of the food at that level. Unfortunately, this information is difficult to determine and may change for every situation. The quantity of lubricant incorporated into food will be different for every process in every factory, and toxicologists routinely struggle to determine absolute levels of safety that apply to every possible consumer in every situation. Further, toxicology studies generally determine Acceptable Daily Intake (ADI) in mg/kg of body weight. Converting this back to the food, requires knowledge about the amount of food consumed and body weight of the individual consumer. In summary, direct calculation is impossible because several unknown variables exist.

A pragmatic approach has been to determine a practical maximum quantity and apply an appropriate safety margin.

21CFR 178.3570

In the USA, the most widely referenced government document for food processing lubricants is the Code of Federal Regulations Title 21 section 178.3570 (or simply 21CFR 178.3570)[v]. This document provides guidance on ingredients approved for food contact lubricants and includes a list of specific compounds and additives. 21CFR178.3570 establishes a 10 ppm limit as the amount of mineral oil (and several other potential lubricant base oils) that can be present in food. There have been no known

incidents under this limit, so the toxicologists' margin of safety appears sufficient at the 10 ppm level. Above that level, the lubricant is considered a contaminant and must be addressed as such.

However, the 21CFR 178.3570 is not specific about the measurement and testing protocols, so it has led to further debate. For example, if a factory makes 1,000,000 cookies daily and each weighs 10 grams the factory can use up to 100 grams of lubricant at the 10 ppm limit. Does this mean that every cookie must contain no more than 100 micrograms of lubricant? Since it is impossible to test every cookie, does the factory meet the standard if they top up the lubricant sump with less than 100 grams of fresh lubricant every day? In cases such as this, companies must use their best judgement to minimize the probability of shipping any contaminated (over the limit) product. Industry should act responsibly to eliminate incidents that can be reasonably avoided. The HACCP principles defined in the next section can help manage the process and determine if further action is warranted.

4. HACCP

Hazard Analysis and Critical Control Point (HACCP) plans are used throughout the food industry to manage risks in the food chain. The earliest roots of HACCP can be traced back to The Pillsbury Company and its work with NASA to provide food for the manned space program in the 1960's. The basic principal is to analyze the entire process and anticipate the steps where hazards may exist. Preferably, these steps can be reengineered to eliminate the hazard. All remaining potential hazards become the critical control points which must be continually monitored and controlled to ensure that the hazard is safely managed.[vi]

A properly functioning HACCP plan will be supported with detailed documentation and reviewed regularly. It is usually the first point of reference for any auditors, so it should be written clearly and provide ample evidence of worker involvement. A plan which stays in the corporate file cabinet will have little value.

This HACCP principal has been widely adopted in the food industry and can actually be used for any operation. HACCP is specifically referenced by the Codex Alimentarius General Principles of Food Hygiene (CAC/RCP-1-1969), US Department of Agriculture Food Safety and Inspection Service (USDA-FSIS), The National Academy of Sciences (NAS), the International Commission on Microbiological Specifications for Foods (ICMSF) and many others.

Contamination with hazardous chemicals would be a potential hazard in any food processing factory. A HACCP plan should list all hazardous chemicals on site and develop a system to document their use to ensure that there has been no contact with the food. Lubricants would be considered hazardous chemicals unless they have been approved for use in food processing, and can be present at trace levels in the food. Therefore, using approved incidental contact lubricants may eliminate a layer of documentation and allow the staff to focus on other critical control points. The most widely recognized food approvals are encapsulated in the "H" categories which cover lubricants and related products.

5. Nonfood categories: H1, H2, HT-1, HT-2, 3H, H3

Most current government activity focuses on ways to reduce pathogens that cause acute illnesses. Reflecting this, HACCP plans may give less attention to nonfood compounds such as lubricants. Many companies prefer to use approved food processing lubricants throughout the plant because HACCP will not consider the lubricants to be hazardous chemicals.[vii] Therefore, the company is not required to account for every gram used. The next question is to determine what lubricants can be used safely for incidental food contact.

History of USDA non-foods program

In the 1970's, the USDA began a non-foods program for various process chemicals including lubricants.[viii] This led to the development of a "white book" listing of approved incidental contact lubricants. However, the USDA stopped publishing their list in 1998, leaving the industry uncertain about the future. Soon NSF International took over the White Book[ix] and gave continuity to the process.[x] Today, NSF International and InS Services have assumed a prominent role by providing third party confirmation that lubricant formulations contain only ingredients that the authorities have determined are safe for the intended use.

Listing of nonfood categories

At present, non-food compounds can fit into one or more of the six finished product categories listed below. InS Services provided the following summary of the categories[xi]:

H1- Lubricant acceptable for incidental food contact

H2- Lubricant where NO food contact is permissible

HT-1-Heat transfer fluid- incidental food contact

HT-2-Heat transfer fluid- no food contact

H3- Soluble oil- to be cleaned off prior to food contact

3H-Mold release agent- direct food contact allowed

There are also sub-categories such as HX1 and HTX1 which are used for lubricant additives and other ingredients. For example, an antioxidant that is approved at 1% additive level in an incidental contact lubricant would receive an HX1 certification. This allows formulators to easily determine which additives they can use to maintain their certification.

After years of development around the H1 standards, there are many excellent lubricants available which can safely be used for incidental contact applications. Although the additional requirements typically add some marginal cost over industrial grades, most feel that H1 lubricants save money in the long run as they reduce the HACCP monitoring requirements and risk of an unfavorable audit experience.

Historically, products in each of the six categories have been marketed as "food grade" although there can be significant differences between the requirements. The number of categories is often cited as a cause for confusion. As an example, several presenters at the recent ICIS Food Grade Lubricants conference reversed the 3H and H3 categories. If experts are unclear, there are doubtless many people involved in the operation and handling that just remember whether a product is "food-grade" or "not food grade" without considering the specific categories. Therefore, well-meaning companies that insist on using food grade lubricants may still use an inappropriate product.

Simplification of the "H" categories

Recognizing the inherent confusion, several within the industry have proposed a simplification of the naming structure. The most common suggestion is to combine H1 and HT1 into a single category and rename 3H to avoid the letter "H". Since H2, HT2 and H3 are not allowed to contact food at any level, these categories would no longer have value and would not be part of the food grade registration scheme. This would leave H1 as the only category for "food grade lubricants". A clear advantage is that lubricants are either food grade (H1) or they are not.

The ongoing debate is not settled as we begin 2016, but the Food Grade Lubricants Working Group of the European Lubricating Grease Institute (ELGI) took the first step by publishing a position paper in 2015 which states that the term "food grade" should only be used for H1 products[xii]. The US based National Lubricating Grease Institute (NLGI) echoed the position paper later in the year.

6. ISO 21469

ISO 21469:2006, "*Safety of Machinery-Lubricants with Incidental Product Contact- Hygiene Requirements*" is a comprehensive standard for food contact lubricants. This was established by the International Organization for Standardization (better known by the international acronym ISO) and last reviewed in 2015[xiii]. It is a product level certification that verifies the formulation, packaging and manufacturing practices are fit for use and provides for a periodic audit to ensure the continued compliance with the standard.

Labels must contain information about the manufacturer, batch specific identifiers, shelf life and appropriate use guidelines. The ingredients must comply with an accepted standard for incidental contact lubricants such as the Joint FAO/WHO Expert Committee on Food Additives, Council Directive 95/2/EC on Food Additives, US 21 CFR 178.3570, GRAS, TOR, FCN or NFC H1 Reg. The company applying must complete a risk assessment to determine possible misuse and other problems that could potentially compromise the safe use of the lubricant and set up procedures to minimize any risk identified. Finally, the facility is audited by a third party who ensures that they manufacture the product under GMP (Good Manufacturing Practices) including handling, recordkeeping, and quality control. Further, the facility should have a Quality System in place that meets the standards of ISO 9001.

Once the products, processes and labelling are vetted, product samples are submitted to build a reference database.

ISO 21469 ensures ongoing compliance through an annual recertification process. This includes a document review, facility audit and submission of samples for comparison to the reference. At present, 21 facilities and approximately 800 certified products are registered worldwide under ISO 21469. NSF International is currently the only certifying body with an ANSI accredited certification program.[xiv]

Brazil has been particularly advanced in its acceptance of the standard and has legislated that all food processing lubricants used in Brazil are registered under ISO 21469[xv].

7. FSMA

The United States Congress passed the Food Safety Modernization Act (FSMA) in 2011.[xvi] The stated goal of the legislation is to shift government attention, allowing them to focus on preventing contamination rather than responding to incidents that have already occurred. It reaches beyond America's borders to oversee the 15% of foods that are imported. FSMA gives FDA a legislative mandate to require comprehensive, prevention based controls across the food supply. Further, FDA has mandatory recall authority for all food products.[xvii] The implementation of FSMA is still evolving as stakeholder partnerships work out effective ways to go from a legislative document to a practical system that maximizes food safety across the country. While FSMA is a significant overhaul of the food industry, there has been ongoing debate about the appropriate interpretation of some sections and concerns about the costs.

8. GRAS

A current debate exists regarding ingredients with GRAS status. The FDA states that any compound which is Generally Recognized as Safe (GRAS) for food is an acceptable ingredient for incidental food contact lubricants.[xviii] Since 1997, the FDA has allowed ingredient companies to make their own GRAS determination without sharing safety data or alerting federal authorities when a new ingredient will be used in the food chain. According to the Natural Resources Defense Council (NRDC), there are 275 ingredients used in food today that do not have adequate information available for review[xix].

In February 2014, the Center for Food Safety (CFS), a public interest group, filed a lawsuit against the FDA to require Federal oversight of this process[xx]. A settlement agreement was reached requiring the FDA to issue a final rule for the process for determining if a food substance can be considered GRAS by August 2016[xxi]. Meanwhile, the Grocery Manufacturer's Association (GMA) is working toward an industry sponsored set of guidelines for determining when materials can be considered GRAS.[xxii]

9. Additional Perspectives

EHEDG

EHEDG is the European Hygienic Engineering and Design Group. Their mission statement is "EHEDG enables safe food production by providing guidance as an authority on hygienic engineering and design for food manufactured in or imported into Europe".[xxiii] EHEDG produces guidance documents that cover

various aspects of food safety. Lubricants are covered in Guideline 23 "Production and use of food grade lubricants, Part 1 and 2 (2009)". Guideline 23 embraces the HACCP principles and confirms their insistence on H1 Category lubricants: "In all cases comprising a contamination risk, H1 registered lubricants should be used. [xxiv]

EC 1935/2004

European regulations for food contact materials are described in Framework Regulation EC 1935/2004.[xxv] This requires that any food contact materials will not affect the safety or quality of food. It also describes appropriate traceability and labelling. This standard does not speak directly toward lubricants but provides a general framework that applies to anything that may come in contact with food.

Concawe and MOCRINIS

The European refining industry formed Concawe in 1963 to address issues of the petroleum industry. Over the years, Concawe has generated extensive data on mineral oil safety, environmental, and health effects.[xxvi] Concawe recently sponsored a workshop of the Mineral Oil Cross Industry Issues (MOCRINIS) to discuss current topics specific to mineral oils. This included discussions on the scientific basis for the safe use of refined mineral oils as food grade lubricant basestocks. [xxvii]

EFSA

The European Food Safety Agency (EFSA) is another resource that issues scientific opinions on topics related to food safety. The European Commission asked EFSA to consider the most recent data and deliver a scientific opinion on the health effects of mineral oil in food. The report shows that mineral oils are a complex mixture of linear and branched alkanes, cyclo-alkanes and aromatic compounds. These are summarized as Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH). Beyond that, mineral oil contains compounds covering a wide range of molecular weight. Toxicity varies widely among the different components so it is impossible to assess exposure limits without specific knowledge of the composition details. The report mentions several potential sources of mineral oil in foods including packaging, printing inks and adhesives. [xxviii] If H1 lubricants are employed at the 10 ppm exposure limit, it is likely that the exposure from lubricants would be relatively small.

GFSI

The Global Food Safety Initiative (GFSI) is an industry driven initiative providing guidance on food safety management systems. The focus of GFSI is to harmonize food safety requirements on a global scale, reducing redundancy and improving efficiency. The main goal is a single certification which would be accepted globally.[xxix] GFSI Schemes address the entire production process and do not mandate lubricants per se. However, Schemes which specify that the process uses H1 products for incidental contact lubricants gain from the de facto global recognition of H1 certification.

Health Canada and CFIA

In Canada, food safety and nutritional standards are set by Health Canada.[xxx] Enforcement is carried out by the Canadian Food Inspection Agency (CFIA). CFIA publishes *The Guide to Food Safety* which follows the preventative approach of the Codex General Principles and accommodates HACCP and ISO food safety standards.[xxxi] On 2 July, 2014, the Government of Canada repealed the pre-registration requirement for non-foods chemicals in federally sanctioned meat establishments. However, facilities are still responsible for demonstrating that lubricants are safe and fit for use. CFIA will continue to maintain the non-food database of their website for reference.[xxxii]

Australia and New Zealand

The Australia New Zealand Food Standards Code covers all aspects of food safety including requirements with regards to processing aids and food additives.[xxxiii] Under the Export Control Act 1982, the Australian Department of Agriculture maintains a list of compounds that are accepted for establishments registered to prepare meat and meat products. The Australian Quarantine and Inspection Service (AQIS) lists approved food contact lubricants as "Lubricant Type A". The list is updated continually as new products are added.[xxxiv]

New Zealand has a separate approval process through their Ministry of Agriculture and Forestry (MAF). This Approval of Maintenance Compound database lists lubricants and other products which have been registered by the MAF.[xxxv]

China

In China, food safety is covered under the Food Hygiene Law of the People's Republic of China. It is designed to protect consumers against contamination and unsafe food handling practices. The main focus is to ensure that harmful substances cannot enter the production area and hygienic food processing conditions exist across the factory. It does not address lubrication directly, but broadly covers all harmful substances which might be introduced into a food production area.[xxxvi]

10. Lubricant Community Involvement

There have been many papers, articles, and presentations on food grade lubricants over the years. For example, NSF International hosts an annual Nonfood Compounds' Steering Committee Meeting at their headquarters in Ann Arbor, Michigan. Also, ICIS recently sponsored the second annual conference on food grade lubricants in Amsterdam. These community resources give lubricant suppliers and food manufacturers the opportunity to become familiar with the requirements of food processing lubricants.

ELGI/NLGI FGLWG

Another industry forum for discussion and debate are the Food Grade Lubricants Working Groups which are jointly sponsored by the ELGI and NLGI at their annual meetings. The FGLWG gives lubricant suppliers an opportunity to develop an industry perspective and working definition of food grade lubricants and establish recommended practices for suppliers. Developing a consensus position will

allow industry to build on government safety initiatives while using the expertise of its members to provide products that are safe for use and also effective lubricants. In 2015, the groups issued position papers to present a unified voice of the industry including best practices.[xxxvii]

As these groups build to a consensus on the code of conduct, the next step is to educate the supply chain on the proper use and practices which will ensure that best practices make their way to the shop floor. Regulations and documents are useless if they are locked in a book or on a website somewhere. The people working in the factory must understand and follow best practices.

11. Trust

The global economy provides safe food to a greater number of people than ever before. For most, there is an implicit trust in the food available. It is important for all parts of the supply chain to act responsibly so that trust is maintained.

Governments provide authority and guidance but are not experts in food processing. All politicians stand for "food safety" regardless of their political leanings and will act in a crisis. While the food industry benefits from clear government programs, it may not want too much government involvement in the details. Government and industry will maintain an easy partnership when there are no food safety incidents. Industry should strive to avoid any crisis by acting responsibly as a standard operational practice.

The food industry focuses primarily on the safety and quality of food ingredients themselves. Lubricants act in the background to keep the factory running smoothly. Although food processing lubricants receive less attention, it is important for food lubricant suppliers to hold food safety above all other concerns. Therefore, lubricant manufacturers should continue to work together to define best practices and ensure that food processing lubricants are properly manufactured and applied. This is the best way for our businesses to keep the trust of the consumers.

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