Improving Food Safety Through updating US FDA GMP Provisions (last updated 1986)

Docket No. 2004N-0230

Written submission by Diana Judge, Shell Lubricants Global Brand & Sector Manager on behalf of SOPUS Products
Dated: 10 September 2004

This submission will cover four proposed rules that Shell believes need to be incorporated into the FDA Code of Federal Regulations in relation to GMP to improve food safety:

?? Proposed Rule One: Use of food grade lubricants in **General Food & Beverage Manufacturing**

?? Proposed Rule Two: Use of food grade lubricants in **Animal Feed Production**

?? Proposed Rule Three: Use of food grade lubricants in **Sugar Cane Crushing**

?? Proposed Rule Four: Use of food grade lubricants in **Wine Grape Harvesting**

Proposed Rule One: Use of food grade lubricants in General Food & Beverage Manufacturing:

"Food grade lubricants should be used in food and beverage manufacturing plants from the time that raw materials arrive until after final packaging to improve food safety. The requirement to use food grade lubricants should be written into FDA Regulation"

Is there a need for this requirement in General Food & Beverage Manufacturing?

Yes. Independent research[1] shows 60 percent of U.S. food and beverage manufacturers are still using non-food grade oils and greases when making food or beverages products, the same oils and greases that are also used in steel mills, mines and trucks. These oils contain additives which are harmful if ingested, and which could potentially end up in food, posing a threat to food & beverage safety in the United States.

Food & Beverage manufacturers in America should be using food grade lubricants in food and beverage processing and yet the research shows 60% are not.

Current FDA regulations have a zero parts-per-million tolerance of non-food grade oil with food. If contaminated by non-food grade lubricants, the food is considered "adulterated".

Shell experience shows that many companies have had lubricant contamination incidents however these incidents go unreported, especially if they are "caught" before the food or beverage leaves the plant. Lubricant contamination is widely perceived as a food quality problem, resulting in taint to the food, rather than the public health risk that it is. For reasons of customer confidentiality, we are unable to disclose the names of the many food & beverage companies that contact Shell on a regular basis seeking to change over to food grade lubricants after a lubricant contamination incident.

[1] Opportunities in Lubricants Volume III Industrial Oils & Fluids 2001, United States Continuing Business Analysis, Kline & Company Inc, Copyright 2003

There are however some local and globally reported product contamination incidents and recalls attributed to non-food grade lubricant contamination which include:

- ?? Sliced Turkey Meat: On June 16, 2000 Farmland Foods Inc, a Kansas City, Missouri, USA firm, recalled approximately 86,000 pounds of sliced turkey inadvertently exposed to a **non-food grade lubricant** during processing. The problem was discovered by the company through analysis of their consumer complaints and a follow up investigation. Consumers complained of off-color, off-odor turkey and some consumers reported temporary intestinal discomfort. Source: www.fsis.usda.gov/OA/recalls/rnrfiles/rnr038-2000.htm.
- ?? Smoked boneless hams: On April 1 1998, Smithfield Packing Co, Kinston, NC, recalled 490,877 pounds of smoked boneless hams after some were adulterated with **gear lubricant**. Several customers reported a "bad taste" and "burning in the throat for up to three hours" after eating the ham. Source: www.fsis.usda.gov/OA/recalls/rnrfiles/rnr008-1998.htm.
- ?? Macaroni & Cheese: In 2001, 142,182 cases of Kraft EasyMac microwavable servings of macaroni and cheese, manufactured by Cloud Corporation, Illinois were recalled, by Kraft Foods. The product was contaminated with a **compressed air system lubricant**. Source: www.fda.gov/bbs/topics/ENFORCE/2001/ENF00687.html
- ?? Bottled Soft Drink : On December 21 1994, Coca-Cola Bottling Company of Buffalo, Inc, Buffalo, New York, recalled 3,616 cases (8 bottles per case) of Coca Cola Classic in 2 litre plastic bottles. The product contained **gear lubricant**. Source: www.fda.gov/bbs/topics/ENFORCE/ENF00356.html.
- ?? Bottled Soft Drink: On August 12th 1992, Coca-Cola Bottling Works of Tullahoma, Inc, Tullahoma, Tenesessee, recalled Coca Cola Classic, Carbonated Cola-Flavored Soft Drink in 10 fluid ounce glass non-returnable bottles, in 16 fluid ounce plastic bottles and in 2 litre plastic non-returnable bottles. Product was contaminated with **gear lubricant**. Source: www.fda.gov/bbs/topics/ENFORCE/ENF00165.html.
- ?? Canned Soft Drink: On October 9th 1990, Coca Cola Bottling Company, Maspeth, New York, recalled 4,000 cases of Diet Coke in 12 ounce cans, packed in 6 pack cases and Sprite in 12 ounce cans, packed in 20 can packages. Product was contaminated with **Dicolube PL, a conveyor lubricant.** Source: www.fda.gov/bbs/topics/ENFORCE/ENF00048.html.
- ?? Bottled Soft Drink: On November 8 2002, a consignment of soft drinks was recalled owing to **lubricant contamination**. The product was "Big Thirst" (five flavors) in 1.25 liter bottles, brought through NQR Grocery Clearance Stores in Victoria, Australia. Food Standards Australia indicated that the lubricant "may cause irritation if consumed". Source: http://www.foodstandards.gov.au/recallssurveillance/foodrecalls/archiveconsumerlevelrecalls/softdrinkchemicalcon1787.cfm
- ?? Infant Formula and Milk Powder: In 2002, Arinco, manufacturers of milk powder at Vidabaek, Denmark (owned by Arla Foods), found 1100 tons of milk powder manufactured between January 3 and June 28, 2002, were contaminated by 0.50 to 0.75 liters of **lubricating oil**, which contained very fine iron particles. The problem was discovered when a customer in Thailand complained that the milk powder had a pale grey tint. Arinco found that the incident had occurred in their packaging plant, where an axle in a gearbox was worn. This allowed oil to seep out through a ball joint and down to the powdered milk. According to the Danish Veterinary and Food Authorities, the contamination did not lead to any health risk to consumers but it did lead to a large recall of several brands of milk powder. East Asiatic Co, to whom Arla was supplying products as an external contract manufacturer, withdrew Dumex's Mamex Infant Formula and Mamil Follow-On from the shops in Thailand. Abbott Laboratories, who also sourced milk powder from Arinco, withdrew Permilac Formula 1 and Permilac Formula 2 from China, as well as their baby milk powder, 'Gain', from the Philippines. East Asiatic Co made a total loss of 40 million dkk (US $6.5m), since their baby food products occupied the

leading market position in Thailand before the incident. They sued Arla for losses not covered by their insurance policies. Source: The Straits Times (July 12 2002); Youth Daily, Shanghai, (July 14 2002); AFX News Ltd (August 26 2002); Philippine Daily Enquirer (July 13 2002).

?? Can of Baby Food: On September 1st 2000, a spokesman from Stoke-on-Trent City Council, U.K., confirmed that tests on a tin of baby food had revealed a toxic substance. He is quoted as saying that the investigations indicated that the tin of Heinz Cheesy Parsnip and Potato Bake was contaminated with **mineral oil lubricant**, possibly from a machine in the manufacturing process or from the can manufacturing process. A mother claimed the food "smelled of tar" and alerted the environmental health officer who took the tin for analysis. Source: The Sentinel, September 1, 2000.

?? Wine Grapes: In April 1996, several consignments of grapes were contaminated by **mineral hydraulic lubricant**, which sprayed during harvesting from a ruptured hose onto the grapes. The incident occurred at the vineyard of EEC Horticulture Ltd, Meenee, and Corbans Wines Ltd vineyard at Haumoana, New Zealand. The contamination was discovered when the harvester broke down at Haumoana. The contaminated grapes were dumped and the incident resulted in legal action by Corbans against the harvesting company (DJ Erickson Farms Ltd) and EEC Horticulture. Corbans Wines Ltd won the case and were awarded NZ $269,609 (US $175,246) plus costs in damages against the harvesting company for negligence. They were also allowed to claim NZ $166,847 (US $108,784) for this amount against the EEC Horticulture. Source: High Court of New Zealand

?? Seasoning: In 2002 Mishima Shokuhin, a major Japanese seasoning company found 55 tons of Furkake seasoning was contaminated with a **mineral lubricant**. The incident was reported in the local paper in Hiroshima. The contamination was only discovered after distribution of the products. The probable source of the contamination was the oil seal of the hydraulic cylinder in the cutter had worked itself loose. Cost of the incident was estimated at GBP 1.1 million (US $1.9m based on retail sale value).

?? Rice Oil: In 1979 an epidemic of a skin disease occurred at a teaching hospital in central Taiwan. Approximately 2000 people were affected and investigations showed they had consumed contaminated rice oil and ingested 1000 mg PCB's (equivalent to 16.6mg /kg body weight) plus 3.8 mg of PCDF's. The contamination occurred when a heat transfer pipe using PCB's as a **circulating fluid** leaked. Following this approximately 270 PCB transplacental babies were born to women affected between 1979 and 1986. In Yen et al's study, results showed the stillbirth rate was five times higher than that of pregnant women in the general population. This was attributed to deterioration of the placental function caused by the poisoning. Infant mortality rates were also significantly higher than that of the general population. The quantity of PCB in breast milk was much higher than that transferred through the placenta, and was likely to accelerate the death of babies. Source: Public domain – Taiwanese 'Yucheng' PCB Episode. Yen et al (1989).

?? Medicine tablets: In July 2002, an FDA inspection revealed the presence of lubricant black specks, combined with metal particles in the specks, on carispordol tablets at the factory of a medicine manufacturer in the US (Medpoint Healthcare Ltd, New Jersey). Studies by consultants attributed the presence of black specks to **lubricant** introduced from the upper cam into the empty die cavity. Trace amounts of metals were attributed to metal abrasion at the tooling keys. The lubricant spotting could be traced back to 1983. Source: www.fda.gov/foi/warning_letters/g3435d.htm

While most product recalls in general result from food-borne bacteria, foreign body contamination (eg insects, wood, metal, stones etc) or processing and labeling errors, nevertheless lubricant contamination plays a costly role. Brand damage and recall costs, as highlighted above, arising from a lubricant contamination incident far exceed the costs of using food grade lubricants.

Why are food grade lubricants necessary in General Food & Beverage Manufacturing?

Machinery used in food and beverage processing have many moving parts that require lubricants to maintain reliable and efficient operation – these range from hydraulics, gearboxes, bearings and chains, to vacuum pumps and compressors.

Food and beverage contamination from lubricants can and do occur from drips off chains (common in bakeries and meat and poultry plants), hydraulic hose failure where oil is sprayed around under pressure thereby contaminating food products being produced (common in meat plants, primary produce & dry food plants), oil leaks from seals and gearboxes (common in any application where there are mixing tanks or gear drives), or a release of compressed air containing an oily mist (compressed air is used to move products around the plant or to force open food packaging bags).

Air compressor Original Equipment Manufacturers indicate contamination from compressed air can be as high as 100 mg oil/m^3 [2]. Even if a well maintained compressor has the correct filters and coalescers in place, it can still carry over 25 mg oil/m^3, while poorly maintained compressors, with no oil filters, or incorrectly fitted oil filters or coalescers in place, will have unspecified oil carry over at a much higher rate[3].

The following document from Kaeser Compressors specifies recommendations on what they think should be used in food plants, dairies and breweries (Type A & Type B systems). All specify a number of filters. In Shell's experience we have not yet visited a food plant with this type of compressed air filtration system in place, and the majority of food and beverage manufacturers are still using non-food grade lubricants in compressors.

"Kaeser Air_Treatment.pdf"

Lubricant contamination of food should be placed in the context of other sources of mineral oil contamination, which could also be avoided by the use of suitable oils and procedures. Areas of food production which have been a cause of concern to the international food community include the use of mineral oil release agents in bakeries[4] (owing to the fact that they work better than vegetable oils), the migration of mineral hydrocarbons from packaging into food (for example, from printing inks[5]), the use of grease on cows udders in the dairy industry, and grain de-dusting in the US (where stored grain is sprayed with mineral oil to avoid the formation of dust and consequent risk of explosions[6]). Given the risk of contamination from such sources and background levels of mineral hydrocarbons in the environment, it is desirable that lubricant contamination should be reduced as far as possible in the food industry.

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[2] Champion Compressors (subsidiary of Atlas Copco Compressors) www.ferret.com.au/articles/e9/0c003ce9.asp

[3] www.kaeser.com/Images/Air_Treatment.pdf

[4] Grob, K. et al. (1991) Food contamination by hydrocarbons from lubricating oils and release agents: determination by coupled LC-GC. Food Additives and Contaminants, 8 , 437-446.

[5] Food Standards Agency, UK (2003). Mineral hydrocarbon in food contact materials (Report 34/3), at http://www.food.gov.uk/science/surveillance/fsis-2003/34fcm; Dionisi, G. & Oldring (2002). Esimtates of per capita exposure to substances migrating from canned foods & beverages. Food Additives and Contaminants, 19, 891-903

[6] Heimbrach, J. et al. (2002). Dietary exposures to mineral hydrocarbons from food-use applications in the United States. Food & Chemical Toxicology, 40, 555-571.

If the risks of contamination and the costs of a recall are so high, why are 60% of food and beverage manufacturers in the US not using food grade lubricants?

We have discovered there are a number of reasons for this:

First: many companies don't know you should be using food grade lubricants and that lubricants can get into the food.

The cessation of the USDA White Book approval system for lubricants has left a void for food and beverage manufacturers when choosing machinery maintenance lubricants for use in food and beverage manufacturing applications.

The US Department of Agriculture (USDA) formerly approved lubricants as H1 ("for incidental food contact") and published the list commonly known as the "White Book." The USDA ceased this acitivity in 1998, and thrid party, Michigan-based NSF International, has since replicated the "White Book" procedures, registering food grade lubricants as H1 food grade in their "e-White Book." (Refer www.nsf.org)

Under US regulations, HACCP leaves the food processor responsible to fully understand the potential physiological risk that a lubricant may pose to the consumer if a contaminated food or beverage is ingested.

As registration of food grade lubricants with NSF by lubricant manufactuers is voluntary, a food and beverage manufacturer either needs to check with a third party certifier such as NSF, or request a written declaration of the formulation from the lubricant supplier in order to check whether the components used in the lubricants are indeed food grade.

The reality is that most food and beverage manufacturers do not know where to go to check whether a lubricant is food grade – nor may they know that food grade lubricants even exist. Shell is also aware of instances where H1 food grade status of a lubricant is claimed by a lubricant manufacturer whereupon further investigation and testing, the lubricant is found not to be food grade at all as per the US FDA Chapter 21 Section 178.3570 regulations.

We recommend that the US FDA keep a list of registered food grade lubricant third party certifiers in order to give greater clarity and comfort to food & beverage manufacturers when they are selecting food grade lubricants. To be on this list the third party certifier must demonstrate that they follow the requirements of the former USDA white book certification system and they regularly conduct random checks to ensure that food grade lubricants registered with them are in indeed food grade and meet the requirements of CFR 21 Section 178.3750.

Second: The majority of American food manufacturers don't use food grade lubricants because they cost more upfront.

However, with technology advances by the development and use of synthetic high performance food grade lubricants, the overall cost of plant maintenance can often be lowered because the lubricant lasts longer and the amount used is generally less – thus improving food safety.

Synthetic oils do cost more than traditional mineral oils (in some instances up to 10 times more), but the initial cost of the synthetic can bring subsequent returns, which mineral oil-based lubricants cannot. Further damages that could arise from not using H1 approved food grade lubricants are immeasurable. They also provide better protection to plant and machinery, which means lowering replacement parts and repair bills.

Synthetic food grade lubricants provide better machinery parts wear protection, thus lowering the risk of metal filings generated by wear, which could end up in the finished food product.

According to the Japanese Institute of Plant Maintenance (JIPM), "up to 65% of mechanical equipment failures can be attributed to some form of lubrication deficiency."[7] The JIPM developed the Total Productive Maintenance (TPM) concept to reach a perfect goal of "zero accidents, zero defects, and zero failures." Lubrication failures can lead directly to production losses, so a robust lubrication program plays an effective part in plant management.

An American beverage manufacturer was able to reduce its maintenance spend by 57% by using a synthetic food grade lubricant. As a result both grease consumption and bearing failures were reduced dramatically thus improving overall productivity levels. The company switching to a food grade lubricant also improved food safety.

Longer oil life from a synthetic lubricant also means a lower number of oil changes – thereby reducing the risk of potential contamination taking place during an oil change. Take for example a New Zealand dairy company that was changing vacuum pump oil 11 times per season using a non-food grade mineral based lubricant. By changing to a food grade synthetic lubricant, they were able to reduce the number of oil changes to 1.5 changes per season – lowering overall maintenance costs by US $17,500 per season and thereby improving food safety by using synthetic food grade lubricants.

Third: There is a perception that food grade lubricant performance is inferior to traditional non-food grade lubricants.

This can be true in the case of some non-synthetic mineral food grade lubricants (medicinal quality white mineral oils) and vegetable oils.

Mineral food grade lubricants are highly refined to remove undesirable aromatic or sulphur constituents – but unfortunately the process also removes beneficial components from a lubricant performance point of view.

Vegetable oils are not designed to deal with the demands of food and beverage processing equipment and can cause issues for the plant when they break down (smell, formation of sludge, growth of bacteria, poor wear protection for equipment etc).

Synthetic food-grade lubricants are odorless, tasteless and generally outperform traditional mineral based food grade lubricants. They are specially engineered for high performance. They remain effective in the sub-zero cold of freezers and the heat of ovens. Their increased oxidation and thermal stability, compared to a traditional mineral or white oil-based food grade lubricant, can extend equipment life and reduce downtime, which lowers maintenance costs.

Field experience and case studies have shown that food grade synthetic lubricants have a longer product life and need to be replaced less frequently in machinery. They are also biostatic, which means they do not promote the growth of nor kill bacteria. This is especially beneficial in dairy plants, bakeries and breweries. In many instances, results demonstrate up to four times more life with synthetic oils. A can seamer, using mineral food grade oil was found to suffer more downtime and bearing failure than with a non-food grade alternative. By switching to a food grade synthetic grease, the canning company not only saved on maintenance in the first year, but also improved the quality of can seam, extended re-lubrication intervals and improved food safety. Synthetic lubricants are also fully compatible with machinery designed for mineral oils. This means that changing over from mineral lubricants is simple, however, a stringent flushing procedure should be followed.

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[7] JIPM Study of 696 Equipment Failures, Copyright JIPM, 1987

Synthetic food grade lubricants today are designed specifically for use in food and beverage manufacturing applications, improving lubrication properties and performance, and offering excellent water resistance.

What is clear is that food manufacturers no longer have to sacrifice plant efficiency for food safety. In fact, they can now reduce overall maintenance costs by using synthetic food grade lubricants.

Fourth: Plants think they have the risk already covered

Independent research (Kline & Co) indicates that 40% of US food & beverage manufacturers do use food grade lubricants. But field experience tells Shell that very few of the 40% of food manufacturers that do use food grade lubricants in the United States, use only food grade in their manufacturing area. It is common for a plant to apply the rule of if it's "above the table" - in other words above where food is being processed, it must be food grade, and if it's "below the table", its acceptable to use non food grade lubricants.

In a plant that has this policy and uses white food grade greases for above the table and red non-food grade greases for below the table, why then are all the grease points PINK?

Beverage Flow Chart.jpg

Mistakes and misapplications do happen and with food safety being a high priority a manufacturer cannot afford to make a mistake by applying a non-food grade lubricant in a food grade application.   It is therefore important to ensure a zero risk approach and use ONLY FOOD GRADE LUBRICANTS from the time that raw materials enter the plant until after final packaging.

When consumed, non-food grade lubricants can burn the back of your throat, cause intestinal discomfort and potentially poison you – this is why the acceptable contamination for non-food grade lubricants is zero. The majority of the ill effects of ingestion of non-food grade lubricants are related to the nature of the additives used in such lubricants. They do not have to meet the requirements of 21 CFR 187.3570, and hence are often formulated using components, which are injurious to human health if ingested.

The mineral oil used in non-food grade lubricants accumulates in body tissue[8], as does white mineral oil used in food grade lubricants. The degree of accumulation in body tissue is highest for the lowest molecular mineral oils (it is for this reason that ADI's for white mineral oil vary according to viscosity).

Synthetic lubricants are usually based upon polyalphaolefins (PAO); tests[9] with rats have shown that PAO does not accumulate in body tissue. Synthetic lubricants also provide better lubrication protection to equipment.

[8] Hard, G. (2000). Short-term adverse affect in humans of ingested mineral oils, their additives and possible contaminants – a review. Human and Experimental Toxicology, 19, 158-172; Noti et al. (2003). Exposure of babies to C_{15} – C_{45} mineral paraffins from human milk and breast salves. Regulatory Toxicology and Pharmacology. Regulatory Toxicology and Pharmacology, 38, 317-325.

[9] European Commission Scientific Committee on Food 2001, "Opinion of the Scientific Committee on Food on hydrogenated poly-1-decene. http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf.

Fifth: Food and beverage manufacturers are afraid to void warranty by using a food grade lubricant

Traditionally very few food and beverage Original Equipment Manufacturers (OEM's) have issued OEM approval for food grade lubricants due to the performance deficiencies displayed by mineral food grade lubricants. The development of synthetic food grade lubricants has helped to alleviate these concerns for OEM's and Shell has been very successful in obtaining OEM approval for its synthetic Shell Cassida range of food grade lubricants in a large range of food and beverage applications.

There are however some food OEM's (e.g. major compressor manufacturers) who do not issue OEM approval for food grade lubricants (including top performing synthetics), preferring to tie their own branded non food grade lubricant to the warranty period, thus food and beverage manufacturers are faced with the decision of whether to sacrifice food safety through the use of non-food grade lubricants or void the warranty on their new equipment.

Proposed Rule Two: Use of food grade lubricants in Animal Feed Production:

"Food grade lubricants should be used in Animal Feed Production from the time that the raw materials arrive until final packaging to improve food safety. The requirement to use food grade lubricants should be written into the FDA Code of Federal Regulations"

Is there a need for this requirement in Animal Feed Production?

Yes. Ensuring high levels of safety and quality should be of particular concern for animal feed producers, whose products impact on the safety of the food chain. In recent years there have been a number of cases of contamination of animal feed, most notably the Belgian dioxin crisis in 1999, where contaminated oil was inadvertently used as a protein source for pellet production[10]. Similar cases have occurred in the U.S., such as in 1997, when natural clay containing dioxin (presumably as a result of contaminated groundwater) was accidentally added to soybean meal as an anti-caking agent[11].

Although not well publicized, contamination of pellets by mineral non-food grade lubricants occurs on a continuous basis in the animal feed industry. The machines used to crush and roll feed pellets operate at extremely high temperatures and require frequent grease and lubricant changes. These greases and lubricants are used on the machine's bearings, joints, linkages and slides and operate in close proximity to the feed pellets, thus increasing the risk of accidental lubricant contact.

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[10] Covaci, A. & Grob, K. (2002). Mineral oil and PCB dioxin analysis in some European food contamination episodes. Eur. Food Res. Technol., 215, 51-54; European Union, Scientific Committee on Food (1999). Opinion on dioxins in milk derived from cattle fed on contaminated feed in Belgium. Expressed on 16 June. http://www.europa.eu.int/comm/dg24/health/sc/scf/index_en.html; Malisch, R. (2000 a). Increase of the PCDD/F contamination of milk and butter in countries of the European Union by use of contaminated citrus pulp. Chemosphere, 40, 1041-1053.

[11] Malisch, R. (2000 b). PCDD/F in kaolinitic clays and its relevance for feeding stuffs, food and cosmetics. Organohalogen Compounds, 47, 326-329.

(Non-food grade grease is pushed out of a bearing as it is replaced by food grade grease)

Non-food grade mineral lubricants are widely used in animal feed production due to their lower cost. However, they contain additives which may be toxic to animals, and which may enter the human food chain.

Recent European Union reform on food hygiene legislation has been designed to increase the safety of animal feed production[12]. Under this legislation, all primary food producers including animal feed processors are obliged to adopt Good Manufacturing Practice (GMP), which involves the use of self-checking programs and Hazard Analysis Critical Control Point (HACCP) audits to ensure maximum food safety. In order to comply, companies have to use food grade lubricants in all critical control points in their plant. A European Code of Practice[13] issued specifically for animal feed manufacturers in 2001 adopts the same approach, with the aim of ensuring that all operators in the food chain assume full responsibility for the products they deliver.

Shell submits that the U.S. Government should adopt a similar approach to that being pursued in Europe, and introduce legislation to ensure that the animal feed industry only uses food grade lubricants in applications where contact with animal food is possible.

Why are food grade lubricants necessary in Animal Feed Production?

Food grade lubricants are particularly necessary in the animal feed industry because there is continuous contamination of pellets in presses due to the current design of pellet presses. This means that grease is supplied to the bearing using either a central lubrication system or manual application. The grease is not safely contained in a receptacle (such as a gearbox, where the lubricant is recycled). It is therefore easier for the lubricant to come into contact with the animal feed.

[12] Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[13] FEFAC Guidelines for the implementation of a code of practice for the manufacture of animal feeding stuffs. European Feed Manufacturers Federation, March 2001, A 10.5 98/1 Rev. 3.

The bearings used in pellet production consume large quantities of grease (approximately 2oz to 5oz of lubricant per press per hour). Since the bearings will always leak grease, it is classified as a lubrication contamination risk.

Open gearboxes are also used in the animal feed industry and are another source of contamination.

Food grade lubricants are necessary in the Animal Feed Industry since they are the most cost effective way of meeting public health concerns.

Proposed Rule Three: Use of food grade lubricants in Sugar Cane Crushing:

"Food grade lubricants should be used in Sugar Cane Crushing from the time the raw materials arrive until after final packaging of the sugar to improve food safety. The requirement to use food grade lubricants should be written into the FDA Code of Federal Regulations"

Is there a need for this requirement?

Yes. Sugar is an important food ingredient.

Why are food grade lubricants necessary?

Traditional mill lubricants are cheap and poor in quality. They have a tendency to form abrasive carbon deposits on bearings and high lubrication rates are required. Food grade lubricants are a far more acceptable alternative, in both economic and environmental terms.

In a typical sugar mill there are several locations where lubricant oil can contaminate the sugar:

(1) The crushing mill

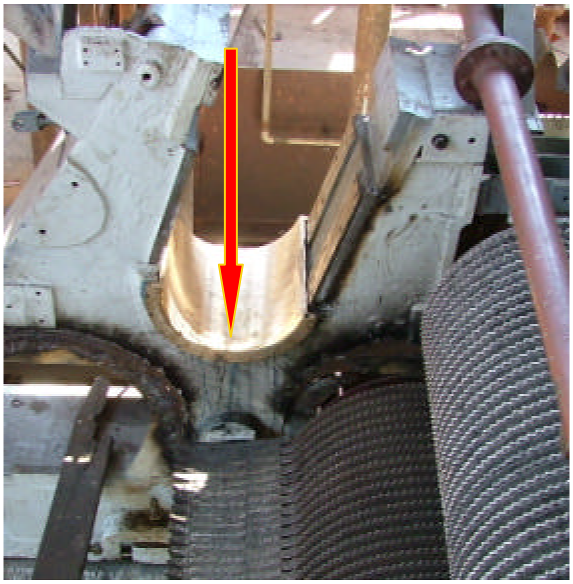
Particularly important is the crushing mill itself, where traditionally black oils such as asphaltic or cardium compounds, often containing harmful chemical components (e.g. long residue oils, asphaltic compounds and heavy metal containing additives (Molybdenum)), are used.

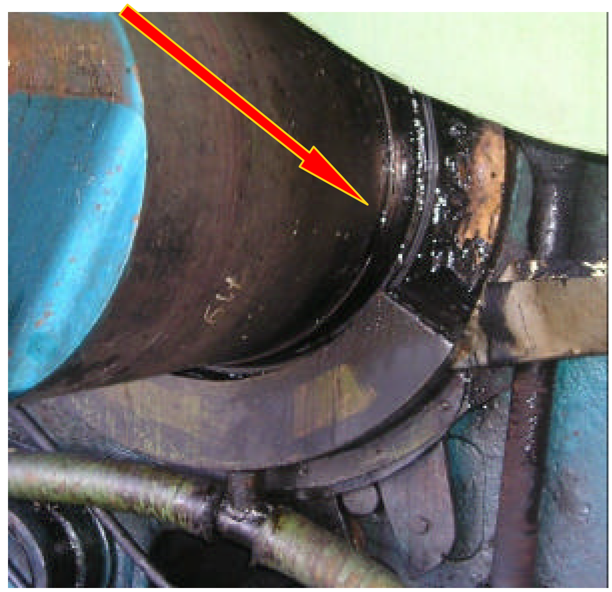
The mill bearings leak oil from seals at each side of the bearing. Mill bearings are a total loss lubrication system; oil or grease is pumped continuously into the bearing (.25 - .5oz of oil is used per 2,000 lbs of cane crushed).

Part of the oil falls outside the mill machine and usually ends up in the effluent water treatment system.

However, oil also falls inside the machine (see Fig. 1) and mixes with the sugar cane juice, which then flows to the refinery. Here much of the oil is separated from the sugar by initial filtration, steam distillation during the concentration of the syrup, and at the point when the crystallised sugar is separated from the sugar liquor in the centrifuges. The majority of sugar from the mill may also be further refined (e.g. to pure white crystalline table sugar). However, it is reasonable to suspect that crude sugar will contain trace contaminants from the mill lubricant. No quantification or analysis of contamination has been reported for crude sugar, but the issue is important since many food and beverage manufacturers use sugar as a raw ingredient.

Fig. 1. *Left*: A view of the inner side of the mill stand, showing the main bearings (a mill in process of re-assembly after maintenance and cleaning). There is clear evidence of past oil leakage into the mill. Oil leaking into the inside of the mill will drop down into the sugar cane juice. *Right:* Here a bearing in operation is leaking asphaltic oil.





(2) The crystallisation process

In the crystallisation process, the product is stirred to promote the growth of correctly sized crystals, and the bearings and any gearbox situated above the centrifuges may be a source of oil contamination of sugar.

(3) The conveyor

The crystallised sugar falls onto a conveyor, which is only partially covered. The risk is oil or grease droplets, from nearby machinery, falling into the sugar.

(4) Drying and milling machines

There is a risk of oil contamination from the lubrication systems on these as the raw sugar is processed.

(5) Packing

The sugar is sometimes packed into sacks that are closed by a machine. Again, there is a risk of lubricant contact with sugar.

The use of higher performance synthetic food grade lubricants in these applications promote reduced lubricant usage, less pollution, less bearing wear and lower maintenance costs.

Proposed Rule Four: Use of food grade lubricants in the Wine Industry:

"Food grade lubricants should be used in the Wine Industry from the time that grapes are harvested until final packaging to improve food safety. The requirement to use food grade lubricants should be written into FDA Code of Federal Regulations"

Is there a need for this requirement in the Wine Industry?

Yes. Shell is aware of contaminated grapes being rejected at various wineries around the world every year. Occasionally the grapes get through to the crushing plant.

A reported incident of lubricant contamination on harvested wine grapes resulted in damages being paid by the harvester to Corbans Wines Ltd. Corbans Wines Limited successfully sought damages against EEC Horticulture Limited (vineyard) and D J Erickson Farms Limited (harvester) for contaminating Corbans and EEC grown grapes with hydraulic oil leaked from a grape harvester's split hose (source: High Court of New Zealand).

The resultant damages paid by the vineyard were based on the previous year's vintage value plus interest and court costs – totaling $NZ 166,847 ($US 108,784). The resultant damages to be paid by the harvester for negligence – totaled $NZ 269,609 ($US 175,082).

Why are food grade lubricants necessary in the Wine Industry?

In many cases the grapes used for wine making have been harvested using mechanical harvesters (see Fig. 2). The mechanical grape harvester straddles the vine and contamination of the grapes with lubricant can occur from these machines, in particular from leaks from the hydraulic systems. Grape harvesters are usually owned and operated by contractors and whilst some of their clients request the use of food grade lubricants, the use of food grade lubricants is rare.

Lubricant contamination can also arise in the grape crushers, which also have hydraulic systems.

If detected, lubricant contamination usually results in the dumping of the affected batch of grapes/grape juice/wine. A common batch size of 80,000 gallons, valued at $4 per gallon (grape juice) to $20 per gallon (premium wine) represents a potential loss between $320,000 to $1,600,000.

Although the main risks are associated with grape harvesting and crushing, there are also lubricant contamination risks at the bottle filling facilities.

(Fig. 2)

(Mechanical Grape Harvester)

Will the use of Food Grade Lubricants Accomplish the Goals of Proposed Rules One, Two, Three and Four?

Yes. With the mandatory use of Food Grade Lubricants from the time that raw materials arrive at a plant until final packaging or during wine grape harvesting, animal pellet manufacture or sugar cane crushing, the goal of reducing the risk of non-food grade lubricant contamination with food will certainly be accomplished.

As stated earlier 60% of US food and beverage manufacturers do not use any food grade lubricants at all.

The US FDA Regulation Chapter 21 Section 178.3570 defines the components that can be used in the manufacture of a food grade lubricant, and also details the maximum allowable contamination levels – the maximum being up to 10ppm for food grade lubricants coming into contact with food as an "indirect food additive".

Shell believes that the allowable contamination limits need to be revisited.

We suggest a way to derive allowable limits for lubricant contamination in food is to start from the ADI (acceptable daily intake) for the base fluid. There are JECFA (Joint FAO/WHO Expert Committee on Food Additives) recommendations for ADI's (evaluations to be found on http://www.inchem.org/pages/jecfa.html) and we have used these as a basis for the calculation of maximum allowable contamination of food by food grade lubricants. In suggesting maximum allowable contamination limits we have assumed that all food consumed is equally contaminated; this is a conservative approach since it is unlikely that all food would be contaminated.

Because ADI's are expressed in terms of mg/kg body weight we have made use of US data on average food consumption and average body weight. The food consumption data was taken from "Foods Commonly Eaten 1994-6", a joint Pennsylvania State University and Agricultural Research Service study (http://www.barc.usda.gov/bhnrc/foodsurvey/home.htm). The average daily consumption of food and beverage in the study was 2.2 kg.

The data on body weight was taken from an analysis of the NHANES III survey representing the US in the period 1988 to 1994 (analysis found at www.halls.md/chart/height-weight.htm). The weighted average of the median weights for the age ranges of the participants in the food consumption study was 60 kg. This gives an average food consumption of 3.7% of body weight per day.

For the purposes of our calculations we have assumed an average consumption rate of 5% body weight per day. Using this value, together with the ADI's recommended by JECFA, we make the following suggestions for maximum allowable food grade lubricant content in food.

For fluids (oils):

Base Fluid type	Base Fluid ADI (mg/kg body weight)	Suggested limit on maximum lubricant content of food
White Mineral Oil (>11 cSt @ 100ºC)	20	400 ppm
White Mineral Oil (8.5-11 cSt @ 100ºC)	10	200 ppm
White Mineral Oil (<8.5 cSt @ 100ºC)	0.01	0.2 ppm
PAO (Hydrogenated Poly-1-decene)	6	120 ppm
Silicone fluid	1.5	30 ppm

For greases, the recommendations depend upon base fluid and thickener type/concentration. The following table relates to some of the more commonly found base fluid/thickener concentrations and assume typical thickener concentrations. In some cases the thickener contains essential elements and hence ADI is not applicable. In some grease, PTFE is used as a thickener – no ADI data has been found for this material and it is not possible to suggest a limit for these types of grease.

Base Fluid type	Suggested limit on maximum lubricant content of food
White Mineral Oil (>11 cSt @ 100ºC)	670 pip
White Mineral Oil (8.5-11 cSt @ 100ºC)	330 pip
White Mineral Oil (<8.5 cSt @ 100ºC)	0.3 ppm
PAO	200 ppm

Measurement of Oil Contamination

It is important to mention that the measurement of oil contamination in all food and beverages at the current maximum FDA levels of 10ppm is very difficult to substantiate. The presence of other contaminants, such as screws and metal bolts, can be detected by passing the food through a metal detector. When it comes to lubricants however it is very difficult to detect small amounts in food or beverage in a continuous process.

Shell has developed various methods of lubricant leak detection including a food grade dye, ultra violet detection technology and laboratory tests that detect trace levels of lubricants in beverages such as beer and soft drinks down to below 10ppm. It is more difficult to detect lubricant contamination in foods such as meat or dairy products due to the natural occurrence of fatty acids and other natural hydrocarbons.

Are There Other Ways to Accomplish These Goals?

The only way to eliminate the risk entirely is to use "oil free" processing and packaging equipment. The European Hygienic Equipment Design Group (EHEDG)[14] has set down guidelines for food & beverage processing equipment manufactured in the EU. The equipment must be manufactured in such a way that lubricant contamination with food is avoided and where lubricants are required, food grade lubricants must be used.

In the U.S. today, the availability of "oil free" equipment is limited and the cost is very expensive when compared to the alternatives.

The risk could be reduced in another way – plant re-design and modification; however, this is again, a capital intensive option that would also incur plant downtime to implement.

The most cost effective method available today, in order to have an immediate impact on improving food safety, is to require the use of food grade lubricants from the time raw materials enter the plant until after final packaging, during animal feed manufacture, sugar cane crushing or wine grape harvesting.

[14] Doc. 23, Production and Use of Food Grade Lubricants, March 2002
www.ehedg.org/doc23.htm

How will this Process Affect the Food or Beverage Manufacturer?

The following steps need to be undertaken to change over a plant to food grade lubricants:

Process	Explanation	Resources required	Costs
Identify all lubrication points in the plant	Plant/Maintenance Managers should already have this information as part of their plant maintenance program – specifying equipment, identifying lubrication points, correct lubricant usage, frequency of lubrication, etc	Maintenance personnel & oil company representative 1-5 days depending on plant size	Between zero to $1,000 per day, depending on what is required
Identify and purchase food grade lubricants	Identify food grade lubricant supplier, confirm all products are food grade (eg refer to www.nsf.org or check with lubricant supplier); purchase product	Quality Manager, Maintenance Manager & Purchasing Manager	1 day maximum
Changeover plant	Drain, flush and dispose of non food grade oil & grease Refill with appropriate Food Grade Lubricants Replace filters and seals in some cases	Maintenance team with assistance from oil company representative (as may be required)	Varies depending on size of plant – small = 1 day; large = 1 week or suggest to build in to progressive change over during scheduled maintenance (eg every 2000 hours). Cost to dispose oil may be higher due to extra volume from disposal of flushing fluids
Re-label machines with food grade lubricants	Machines clearly labeled to indicate which food grade lubricant should be used	Maintenance team	Cost of labels – estimated at $20-$200 depending on size of plant
Lubrication storage and dispensing equipment	Using old grease guns or oil pourers which have been contaminated by non-food grade products is inappropriate and these would need to be replaced. Lubricant storage tanks would need to be drained and flushed	Maintenance team	Varies depending on work required. Average cost of a typical grease gun, $50. Lubricant dispensing containers, average $10 each. Storage tanks depend on size etc. (Note: Most food grade lubricants are sold in drums, pails or tubes)
Staff Training	What is a food grade lubricant? How to handle a food grade lubricant?	Maintenance team and Oil company	Varies depending on what is required – zero to $1000 per day

What is the Cost Impact & Analysis for General Food & Beverage Manufacturing?

Shell estimates the impact of the costs of this proposal as follows:

1. Food grade lubricants cost more per gallon or pound than non food grade lubricants – but (as detailed above) using synthetic food grade lubricants can save a food & beverage manufacturer money overall, by reducing their parts and maintenance spend, while also improving food safety.
2. Changeover impact – the cost to food manufacturers in changing over a plant is relatively small aside from the initial spend on food grade lubricants and flushing fluid, as the change over could potentially be managed in line with routine oil change service intervals.
3. In Shell's experience, the cost of a company's lubricant spend is generally between 3-5% of the total maintenance budget, and the volume of lubricants used is relatively small.

Company Size	Estimated average lubricant usage	Estimated* incremental of using food grade lubricants
Small	200 gallons	$1200
Medium	1,000 gallons	$6000
Large	20,000 gallons	$120,000

*Based on the average current sale price of white mineral food grade lubricants in the U.S.

4. The cost of just one recall or a damages suit (as per the reported examples above) as a direct result of a lubricant contamination far outweighs the cost of lubricants.

What is the Cost Impact & Analysis for Animal Feed Production?

Shell estimates the impact of the costs of this proposal as follows:

Pellet press bearings can only operate on a total loss basis – i.e. the grease needs to be constantly replenished in order to lubricate the bearing. The environment is extremely dusty (from the animal feed), so the flow of grease through the bearing is required to keep the bearing free from contamination and dust.

Company Size	Estimated average lubricant usage	Estimated* incremental cost of using food grade lubricants
Small	3,000 lbs	$15,000
Medium/Large	45,000+ lbs	$90,000

*Based on the average current sale price of white mineral food grade lubricants in the U.S.

Unfortunately, this proposal results in a higher cost if animal feed production converted to the use of only food grade lubricants. Owing to its importance for public health, animal feed production should be better regulated. The European approach to regulation of the animal feed industry, based on HACCP and the use of food grade lubricants, could be a suitable approach for the U.S. government to adopt.

The cost of just one recall or a damages suit (as per the reported examples above) as a direct result of a lubricant contamination far outweighs the cost of lubricants.

What is the Cost Impact & Analysis for Sugar Cane Crushing?

Despite their higher initial cost, food grade lubricants can be cost effective over the longer term. Overall savings can be achieved by the following:

Lower oil consumption: In a field trial in Colombia, using a food grade lubricant compared to an asphaltic product, 50% savings in oil costs were achieved (US $2,500).

Lower maintenance costs: Trials over a five-year period in Brazil and Columbia suggest that savings in repair of gears using some food grade oils can be as high as US $50,000 per year for a typical mill.

Increased energy generation: Many mills generate their own energy from bagasse. The reduced energy consumption benefit from using food grade lubricants increases the amount of energy that can be sold to the grid or lowers the requirement to purchase additional energy. These savings or the income generated can be higher than the cost of the lubricant. Increased energy efficiency obtained through the use of one Shell product resulted in a saving of 1% of the power used to drive the mill.

Savings on environmentally related expenditure: Some of the lubricant used in the total loss application in the main mill bearings will leak out of the bearing and onto the mill floor, or into drainage channels, and find its way into the mill effluent water. Similarly, lubricant, which drips or is flung off the open gear pinions will end up in the wastewater. This has to be treated as industrial effluent water.

During heavy rain (not uncommon in sugar cane growing areas) there is the risk of oil-contaminated effluent water mixing with storm water and causing a pollution incident. Thus, biodegradable lubricants for these applications are important (in Brazil, large fines are payable for oil in effluent water).

Some food grade lubricants are "inherently biodegradable" and degrade more readily than non-food grade synthetic gear fluids and mineral asphaltic products. This reduces the costs of clean up from pollution incidents and lowers the costs of wastewater treatment.

There are some additional costs related to the conversion to food grade lubricants – adjustment to the lubricant application system, flushing and tank replacement.

What is the Cost Analysis for Wine Grape Harvesting?

Shell estimates the impact of the costs of this proposal as follows:

- A winery picking 500,000 lbs. of fruit from 50 acres of vines, with their own mechanical harvester, and producing 20,000 cases of wine per annum from this fruit; if converted to food grade lubricants, the approximate annual lubricant consumption would be
  115 gallons, at an incremental approximate cost of $690 to $4,140 per harvester, depending on what type of food grade oil is selected.

The cost of just one recall or a damages suit (as per the reported example above) as a direct result of a lubricant contamination was US $284,030 – far outweighing the additional cost of food grade lubricants.

SUMMARY:

It is a concern that 60% of U.S. food manufacturers still rely on non-food grade conventional lubricating oils and greases to lubricate their food and beverage production machinery. It is either because they do not know about the need to use food grade lubricants or they have tried food grade lubricants and have reverted to using non food grade lubricants because the food grade lubricant could not handle the application.

With the technological advances that have taken place through the introduction of synthetic food grade lubricants, food manufacturers no longer have to compromise plant efficiency for food safety. There is something that can be done about reducing and eliminating this food safety risk, however legislation is required to enforce.

It is imperative that the FDA extends current food and beverage safety regulations to meet today's changing needs, including more rigorous oversight and quality assurance standards that match programs adopted widely in other parts of the world.

Assuring the safety of the food supply goes beyond the borders of the United States and therefore the U.S. should embody the highest universal standards of compliance, quality and safety at every stage of food and beverage manufacturing.

RECOMMENDATIONS:

?? For greater food safety in the United Sates:

Proposed Rule One - Use of food grade lubricants in General Food & Beverage Manufacturing: "Food grade lubricants should be used in food and beverage manufacturing plants from the time that raw materials arrive until after final packaging to improve food safety. The requirement to use food grade lubricants should be written into FDA Regulation"

Proposed Rule Two - Use of food grade lubricants in Animal Feed Production: "Food grade lubricants should be used in food and beverage manufacturing plants from the time that raw materials arrive until after final packaging to improve food safety. The requirement to use food grade lubricants should be written into FDA Code of Federal Regulations"

Proposed Rule Three - Use of food grade lubricants in Sugar Cane Crushing: "Food grade lubricants should be used in food and beverage manufacturing plants from the time that raw materials arrive until after final packaging of the sugar to improve food safety. The requirement to use food grade lubricants should be written into FDA Code of Federal Regulations"

Proposed Rule Four - Use of food grade lubricants in the Wine Industry: "Food grade lubricants should be used in food and beverage manufacturing plants from the time that grapes are harvested until after final packaging to improve food safety. The requirement to use food grade lubricants should be written into FDA Code of Federal Regulations"

?? The maximum contamination levels of mineral lubricant in food as prescribed by CFR 21 Section 178.3750 should also be reviewed to ensure that these are made more realistic and workable.

?? The US FDA should keep a list of registered food grade lubricant third party certifiers in order to give greater clarity and comfort to food & beverage manufacturers when they are selecting food grade lubricants. To be on this list the third party certifier must demonstrate that they follow the requirements of the former USDA "white book" certification system and that they regularly conduct random checks to ensure that food grade lubricants registered with them, are in indeed food grade and meet the requirements of CFR 21 Section 178.3750.

It is only with proactive FDA support through updating these regulations that we can work together to reduce and eliminate these food safety risks.

Thank you for the opportunity to make these comments. Should you require any further information or have any questions in relation to this submission, please do not hesitate to contact the writer.

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