









Outline

- Refreshing the basics
- Current challenges from the market
 - MOSH and MOAH
- Future challenges from legislation
- Full plant lubrication and HACCP
- Conclusion
- References







- Technical consideration
 - A food grade lubricant H1 needs to fullfill the same technical properties as any industrial lubricant for the same application.
 - Additional care needs to be taken when selecting the lubricant as not all industrial chemistries are available for food grade lubricants.
 - Lubricants should be an integral part of the HACCP of any food stuff producer.
 - A food grade lubricant is a product that complies with special legal regulations, voluntary regulations, production site certification and (often) religious regulations.







- Food grade lubricants versus industrial lubricants
 - Legislation
 - Regulations
 - Certifications
 - Production
 - Formulatory limitations.







- EU
 - No legislation for the use of lubricants so no contamination maximum levels determined.
 - HACCP and GMP where lubricant use is as little as technical feasable.
- USA (Global)
 - The US lead system is followed globally by food stuff producers as well as lubricant producers.
 - System based on the FDA 21CFR codes of federal regulations.
 - USDA created a system of registrations known as H1; H2; H3; for lubricants and 3H for mould release.







- USA cont.
 - USDA discontinued registration in 1999. Now done by NSF (INS) with similar process.
 - H1; H3, and 3H are NOT mentioned in the applicable 21CFR.
 - Can lead to some confusion
 - Need to read the applicable 21CFR for full use and limitations of a product.
 - H2 is not based on any 21CFR.
- H1 etc are registrations. Formulation review but no audit.
- ISO21469 is an audited standard for lubricant production. Part of this is the verification that the H1 produced product is similar to the registration.







- Religious certifications
 - Most common are HALAL and Kosher.
 - Formulation, production and filling are audited.
 - In many markets these certifications are equal or more important than the H1 registrations.
 - Always must be in combination with H1 etc. to safeguard your intention to have a food safe lubricant.





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Refreshing The basics

Production.

- Dedicated blending tanks.
- Dedicated filling equipment.
- Stainless steel tanks and pipes.
- Measures to protect room environment.
- Traceability and documentation.
- Packaging material suitable for food.
- HACCP working practice.
- ISO21469 certification







- Formulation limitations.
 - Not all base oils are allowed for H1 lubricants
 - Not all additives are allowed for H1 lubricants
 - Additives are limited in their percentage present
- Need to find synergies between additives to get desired performance within the formulatory limitations.
- In some applications formulation limitations lead to reduced performance compared to industrial lubricants.







- Political and financial
 - Sudden boycotts
 - trade barriers and tariff wars
 - Supply disruptions due to limited sources of raw materials
- Increased cost for registration
- Need for ISO21469, extending the ISO 9001 or separate certification
- Relative high cost per liter of lubricant. Registration and certification cost and small scale production in dedicated installations.
- Pressure from NGO on Mineral Oil Hydrocarbons. The ongoing MOSH and MOAH misleading discussion. Customers demanding guaranteed MOSH and MOAH free product.













- MOSH and MOAH
 - Affecting all countries supplying into the EU (at the moment).
 - Worries based on older information that has been revised.
 - Large evidence based documentation supporting the safe status of MOH based lubricants and food additives.
 - All mineral base oils need to have a pass on the IP346 proving the elimination of the cancer potential PAC.
 - Mineral Oils are in effect Highly refined mineral oils, not the black stuff.
 - Mineral oils have a proven record of beneficial effects in pharmaceutical use. Similar products are used as base oil in lubricants (pharmaceutical grade white oils or close to this spec as technical white oils).







- MOSH and MOAH
 - Analytics of final food often lead to wrong conclusions.
 - The current methods distracting Mosh and MOAH from food are not sturdy enough and give merely an indication.
 - The MOSH and MOAH found in the final food will not show the source of the molecules found. This can be from many sources including nature itself. (example skin of an apple).
 - A base line analysis normally is missing on food MOH analysis.
 - MOH, 3H pharmaceutical mineral oils could have been part of the production of intermediates in the food production. So you will find them in the final food.
 - But we know that the very highly refined mineral base oils used in lubricants are safe!



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Future challenges.

- MOH has seen a lot of pressure from NGO and subsequently government initiatives.
- This is only one of the few base oils used in food grade lubricants
 - How about PAO, PAG, POE, AN, etc.
- The studies and data collection for the MO was very expensive and time consuming. This was possible due to its double use as pharmaceutical product as well as lubricant base oil.
- Similar work on other base oils will be less likely due to the smaller volumes causing excessive costs per liter.
- And how about additives?
- It is likely that the NGO business model will continue to cause pressure on our industry.





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Future challenges

- What will the FDA do?
 - For incidental food contact M.O. base lubricants the maximum is 10 p.p.m.
 - How can this be policed?
 - Analysis will prove difficult (ref. to mosh and moah analysis)
- What will China, Japan, Korea, Australia, Canada, Brazil etc. do?
- How to deal with many possibly different legislations in a global market?
- What will be the cost effect on small volume lubricants in a global market?
- Lubricants will remain vital for mechanized food production, including agricultural applications.







Full plant food safe lubrication.

- H1 Food grade lubricants are safe solutions when used in their intended way.
- The products are "for incidental food contact" so they are not an approval to ignore leakages. When product is missing it is likely to go into 2 possible areas.
 - On the floor, causing a risk for staff.
 - In the food stuff, causing an unacceptable addition to the food, but not necessarily a human health risk.
- Avoid use of H2 lubricants as these are not for incidental food contact even when carrying the NSF logo.
- Make H1 lubricants an integral part of the HACCP.







Full plant food safe lubrication.

- Measuring the actual ingress of lubricant in the food stuff is not accurately possible.
- We can calculate lubricant top-up in relation to produced food stuff.
 - 1 kg of lubricant in 100 MT of food relates to 10 p.p.m.!
- Measuring oil levels on a daily basis is a must.
- Reporting oil top-up is a must.
- In case of leaks immediate repairs should be initiated.
- For nearly all industrial oils there is an H1 alternative available.
- Only H1 products in a plant reduce risk of errors.







A buyers guide for FGL.

- Product must be registered H1. (NSF, INS or other)
- Producer should be able to show production under ISO 21469.
- Have documents showing the compliance with the registrations.
- Product should meet technical requirements, so select a reputable partner that can be of help here.
 - Different properties with different base oils.
 - Good performing lubricants save maintenance cost and can avoid unplanned production disruptions.
 - The cheapest product is not always the best solution but neither the most expensive one will be the better solution.
- Product should likely meet HALAL, Kosher or both.
- Select a lubricant partner that can assist in training for the use of lubricants and incorporation into the companies HACCP.
- The buyers need to ask the right questions and must inform themselves.







Concluding

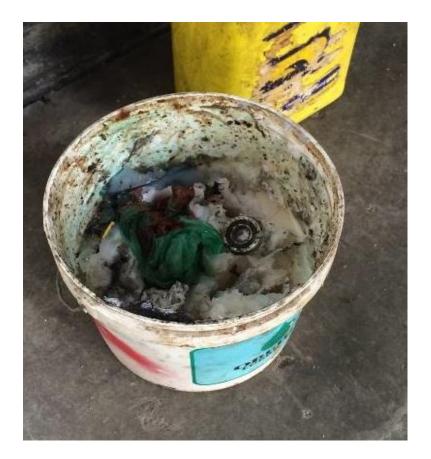
- Much more training and education needs to be done by all parties in the market.
- False or misleading claims need to be countered. Example MOSH and MOAH free mineral oils do not excist.
- Highly refined mineral oils do not cause cancer.
- Mineral oil free lubricants will not lead to MOSH and MOAH free foodstuffs.
- Google is likely the basis for the MOSH and MOAH problem to continue for a long time. Many organisations and papers copied the original wrong articles and as result they score higher in the "hit list" than the scientific articles countering these false claims.
- Modern food grade lubricants are safe, support HACCP and are technically capable of doing what the were designed for: lubricate.







Behavior and training









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