THREE THINGS TO CONSIDER FOR RELIABLE, REGULATORY-COMPLIANT FOOD APPLICATIONS

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INTRODUCTION

With the human population rapidly expanding, the subsequent demand for food products is forecasted to increase by 70% to 2050[1]. In real terms, this equates to a staggering 2.7 billion more mouths to feed in the next 30 years. The population will then require more food than all of the food produced during the previous 10,000 years[2]. This means that to meet demand at this incredible scale, food companies will be looking to make products that can be mass produced economically and safely. Equipment suppliers will be challenged to not only keep pace with this growth but also present new solutions to increase productivity, reduce downtime, lower costs and allow for innovation. A tall order to fulfil.

For the near term future, it is predicted that manufacturing of 'innovative food types' will be a main driver for food companies looking for revenue growth[3]. Demographics shifting to a more aging population and greater urbanization, acceptance of food substitutes and healthier options, and the growth of smaller manufacturers and instant ordering have all been predicted to influence consumer preferences and ultimately the food types that will be produced[4].

Food processing and handling (FP&H) equipment is an industry that has outperformed the industrial sector by approximately two fold over the last 5 years[5]. It continues to demonstrate strong growth credentials underpinned by key global trends. Therefore is an exciting but challenging sector for manufacturers to be involved in.

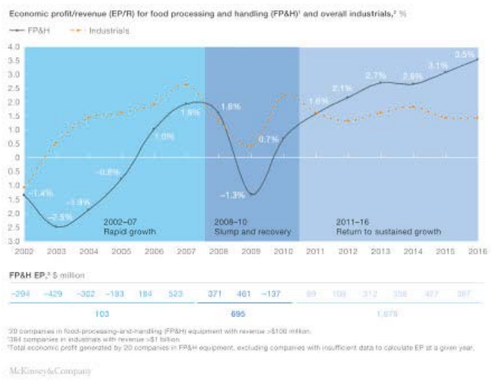

Figure 1. Economic profit/revenue for FP&H and Overall Industrials (Excerpt from ref 5)

Figure 2. Population Increasing

CHALLENGES FOR MANUFACTURERS

The main purpose of this article is to highlight the potential that modern materials have in helping address some of the challenges faced today by FP&H equipment manufacturers. Three considerations include:

1. Regulatory and Quality compliance
2. Increased performance requirements
3. Cost reduction of parts

Regulatory and Quality compliance is the backbone of the industry and the landscape is continuously evolving. One consequence for industrial food processing is the presence of cleaning-in-place (CIP) or sterilize-in-place (SIP) processes, to ensure a compliant, clean, safe and high quality process line. CIP and SIP conditions place demands upon equipment that continually tests the limits of many traditional materials over many cycles of use.

Increased performance requirements are often due to things such as

- Evolving food products
- Increased lifetime
- Enhanced productivity levels

Modern food products are changing in the way that they are formulated, but also in the way in which they are produced (for example, the introduction of high pressure processing of foods). Both aspects ask new questions of the equipment and the materials of construction. Demands from food companies for lower manufacturing costs and increased product yields mean that FP&H equipment manufacturers have to develop equipment that can run for longer with reduced downtime, whilst being more efficient and safe.

Cost reduction of parts: Equipment manufacturers must deliver parts that last longer and/or work better and/or cost less. In the short term, the cost of component parts can be influenced by the manufacturing cost of parts – components may require costly multi-step machining to manufacture or utilize materials that are difficult to handle.

Selection of alternative materials or scaleable manufacturing processes, such as injection moulding can reduce component cost. In the longer term, the total cost of ownership for parts can be reduced by the selection of more optimal materials or designs that prolong lifetime and cut costs in downtime or loss in product quality.

Figure 3. Indoor view of beverage factory

1.

REGULATORY & QUALITY COMPLIANCE

All materials used in the construction of food processing equipment (eg. coffee machines) or production machinery (eg. process lines) must typically adhere to the legislation from the European Food Safety Authority (EFSA) and the US Food and Drug Administration (FDA). Whilst the EU and the FDA have been the preeminent authorities in recent years; Mercosur regulation has been in effect in South America, and more recently China imposed a new regime of GB norms for food contact in May 2016 and Japan implemented a positive list of food contact substances in June 2020.

The majority (82%) of the US companies reported that the Food Safety Modernization Act (FSMA) from the FDA was the regulation and mandate they were most focused on and concerned about, with only two thirds feeling prepared adequately[6]. To support this, all materials need to be manufactured in a compliant way and also evaluated appropriately to see whether they present any safety concern during their use. Compliance with this continually evolving legislation is important, since the materials could create an adverse effect on the food in contact with them.

The EU framework regulation 1935/2004 set out the original requirement for all food contact materials (FCM). EU 10/2011 enhanced the regulatory governance specifically for plastics and recent most notable changes have included

- the creation of a list of plastics (the Positive List) permitted for use in contact with food.
- increasingly stringent specific migration limits (SMLs), now set at part per trillion levels for perchloric acid salts.
- increasingly extreme test methods, designed to expose potential flaws in material or migration of toxic species under more extreme conditions. For example, the hot oil migration test has elevated the protocol temperatures from 175°C to 225°C, as this increase can influence migration of toxic species and/or the decomposition of the plastic.

Strangely, the regulation governing other material classifications such as metals does not appear to have moved forward to such an extent to date. Whilst the plastic SMLs are controlled under EU 10/2011 and include evaluating the heavy metals such as lead (Pb) and nickel (Ni), which are rarely contained within plastics, those same species are not controlled to anything like the same level in metal systems, where they more commonly occur. This can surely only be a matter of time before similar regulatory controls impact these metal based systems.

Another example of increasingly stringent regulations is EFSA's ruling on BisPhenol A. This concern has gained widespread publicity in the media[7], particularly with regard to plastic baby and drinking bottles. EFSA amended Regulations such as EU 10/2011 to ensure that migration limits for harmful chemicals coming from materials are tested according to the current scientific advice[8]. The challenge for equipment manufacturers means that their choice of trusted materials for construction is limited and only certain materials can be used for certain applications. In some respects this constrains the design freedom of OEMs, since engineers are limited by the properties of the materials available to them.

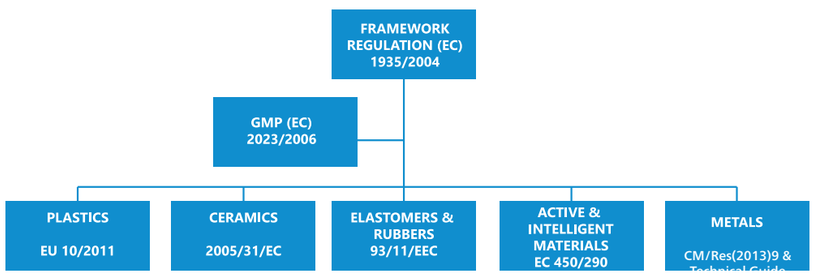

Figure 4. Summary of food contact materials regulatory framework in Europe

STRINGENT REGULATIONS

Development of more stringent regulation will undoubtedly continue in the food industry. This has been the case for the other areas governed by regulators, such as the medical device regulations, and we may be able to learn from experiences here.

In medical, regulation has developed a greater emphasis and responsibility has been placed upon the supply chain. OEM sourcing managers who rely on their suppliers through the outsourcing of component manufacturing and critical services, are becoming even more dependent upon their supply base in order to achieve and maintain their own compliance. Materials, article, parts and equipment suppliers need to understand their new responsibilities and have the required systems and resources to support compliance activities. Some prudent things for OEMs could be reviewing their current suppliers for assurance that they are properly aligned to the likely incoming industry regulations, and are willing and able to take on the additional requirements, cost and obligations. Increased regulatory burdens and costs could mean that some critical suppliers are lost. For OEMs, partnering with the right suppliers as early as possible will significantly reduce these risks and burdens.

Figure 5. Mordern Laboratory

COST OF COMPLIANCE

The cost of compliance is significant. The addition of new materials approval under FDA and EFSA can often exceed £100k for each and take well in excess of a year. This does not include the in house application testing and validation in the given application, or indeed the food contact approval of the device. Some de-risking of those costs is available where the material supplier has already certified their materials with NSF (National Sanitation Federation) to the NSF/ANSI 51 standard which establishes requirements for materials used in the construction of commercial food equipment based on US FDA regulatons . Pre-approved materials can deliver cost savings in the region of £10k and time savings of approximately 12 weeks.

Microbiological or physical contamination during manufacture is, of course, a primary concern for food companies, who can mitigate these risks through quality procedures and cleaning in place (CIP). For equipment manufacturers supplying them, the selection of the most suitable materials of construction for the equipment can help by making hygienic design (eg. EHEDG) easier to implement, or the materials being unaffected by cleaning or ensuring that the materials are resistant to degradation so that they themselves do not become the contaminant. Process line equipment not only has to withstand the food product ingredients and food processing operating conditions, but additionally need to withstand the rigorous CIP cycles in-between batches, which use chemicals, temperature and steam. Whilst the materials may be tolerant of the food process, they may be adversely affected by these frequent CIP cycles. Adhesive or viscous foods may not present an issue in themselves but their residues may present a health or fire hazard if not thoroughly removed.

Dairy and juice based and cold fill products processed in aseptic lines are the fastest growing sub sector in aseptic processing. The trends appears driven by consumer reaction to carbonated drinks and awareness of health and wellbeing. These processes place a challenge on the materials used for equipment. For dairy products the growth has resulted in high amounts of capital expenditure occurring, reflected by US shipment values of dairy equipment increasing by 43% over six years[9]. Equipment manufacturers supplying into higher risk of spoilage dairy product lines can look to materials meeting additional best practice guidelines, such as the 3A certification, which can add further reassurance that the materials are the best fit for purpose.

Given the constantly shifting regulatory landscape, the time and cost involved in certification, it makes sense to work with materials that possess a clean bill of health and with suppliers that understand the industry and are in compliance with global standards and regulations.

2.

INCREASED PERFORMANCE REQUIREMENTS

Evolving food products and processes are calling upon equipment to do more extreme things. New recipe formulations are presenting more aggressive ingredients and processing conditions are frequently operating at higher levels, both of which can place new demands on the equipment and materials handling them.

Common food types that test the current boundaries often have ingredients with one or more of the following aspects: higher alkalinity, high metal salt concentrations, adhesive viscous or sticky ingredients, crystalline or particulates, or belong to higher contamination risk groups such meat, poultry, seafood and baby foods.

Pressures to make processes more economical over time to recoup costs and reducing any downtime, due to performing maintenance, are factors that can be affected by the materials of construction.

More versatile, modular units are a competitive advantage for equipment providers, to allow their machines to be used in multiple, customized process line configurations. Ease of changeover to reduce downtime and quickly integrate into a line is also key. This ability helps meet the increasing number of SKUs that food companies typically have. However these desired additional requirements place new demands on the equipment and the materials they are made from.

Figure 6. Bottled water production

Developing equipment that is compatible with the growing areas of automation and connectivity through the Internet of Things (IIoT) and is necessary in order to enhance productivity and future-proof the equipment. Automation of equipment is increasingly prominent, to aid lean manufacturing and maximize efficiencies. Robotics are becoming more widespread outside of the packaging operations where they are so prevalent. Smarter equipment is becoming available, at lower costs, to perform self-diagnosis and preventative maintenance cycles in order to reduce risks of failure and downtime. In addition, there is increasingly sophisticated inspection equipment with faster read times and throughput, whilst detecting contamination at even higher resolutions. All of these developments ask new questions of the materials used in the manufacture of the equipment.

The majority of companies (94%) measure Overall Equipment Eff ectiveness (OEE), to better understand the performance and running of an operation and to identify how and where they can improve efficiencies[10]. Equipment and parts that can run longer, are lighter in weight or use less energy when operating are all potential ways to increase efficiencies. The increasing demands for improved taste experiences, longer shelf life, clean labels, product differentiation and consumer safety mean that exposure to extreme concentrations, processing environments, and cleaning conditions are increasingly more commonplace. Therefore there is an evolving criteria for use placed upon the materials of construction. Common process condition extremes are temperature, pressure, wear and abrasion and chemical concentrations. Consequently, the demands being placed on the materials of construction are changing as a result of these evolving processes and ingredients.

3.

COST REDUCTION OF PARTS

According to McKinsey and company, the earnings before interest, taxes and amortization (EBITA) margin in the FP&H sector have improved from 5.5% (2002-07) to 10.2% (2011-16), alongside a 4.3% CAGR in revenue[5]. Whilst several factors contribute to this improved performance; effective cost reduction is an important lever.

Cost reduction can come in many forms:

- raw materials input cost
- reduced component cost
- reduction in maintenance
- reduction in waste / increase in yield

The most effective cost reduction contribution considers the overall impact on profitability and consequently decisions are driven by total cost of ownership model, rather than merely the per kilo cost a raw material.

Plastics offer a range of cost effective solutions, with the bonus of low cost injection moulding solutions that often deliver a lower component cost versus metal, despite a higher raw material cost. High performance plastics can perform similar to metals, with the bonus of greater resilience to corrosion; delivering reduced maintenance, lower downtime and thus higher productivity. Migration from manual labour to automated, smart systems and even robotics are an increasingly attractive option given the increasing costs of labour and the decreasing cost of advanced automation. Reduction in the total cost of ownership is a key concern for food processors and a pressure passed on to equipment manufacturers. Demands on equipment efficiency and reduction of downtime and waste (whether product, part or power) mean that parts need to perform better, last longer and be cost effective when replaced. Therefore the lifetime and performance of parts and equipment are important to help keep the operating costs down, whilst increasing yields.

Figure 7. Croissant production

Figure 8. Filling nozzles

Figure 9. Biscuit and waffle production

FOOD CONTACT MATERIAL OPTIONS

Traditional limitations

Traditionally the choice of food contact material (FCM) options has been limited by their ability to meet safety requirements and then whether they are fit-for-purpose from a performance and cost perspective. This has naturally limited the choice to a fairly small group. Commonly used materials include the plastics PTFE (Polytetrafl uoroethylene) and PEI (Poly EthylenImine), and the metals stainless steel and brass, but often the choice comes with a compromise.

For many structural parts requiring strength, metals are an excellent option but have limitations where weight or temperature conductivity may be a concern and will add energy costs. Traditional wear components manufactured from metals also often require an additional lubricant which can be a potential contaminant. Metals are also prone to attack from chemicals, including food ingredients containing higher levels of metal salts such as sodium and calcium.

For applications that require a toughness and resilience or are being used in tribological wear situations, then polymers off er many benefits. Soft materials like PTFE are known for low friction and chemical resistance, but have lower tolerance to wear and abrasion and have relatively poor mechanical properties. Stronger and harder polymeric materials, like PEI, have good mechanical performance, but have limitations to withstanding aggressive chemical exposure. Additionally, applications requiring long-term loading can cause problems with amorphous materials like PEI - as they can creep and fatigue over time.

Naturally, the selection of the right food contact material is critical for the equipment to be fit-for-purpose. As the FP&H equipment market needs have evolved, so too have the requirements for materials of construction. Due to the particular demands placed on food contact materials, traditionally there has been a limited choice available to equipment manufacturers. However, like the processes and foods, the materials have also evolved and today it should not be assumed that the traditional materials are the only choice.

MODERN MATERIALS ARE REQUIRED FOR MODERN SOLUTIONS

High Performance Polymers

High performance polymers are being used as the materials of construction to make critical components and equipment in many demanding industries. They are often used as an alternative to metals. This family of polymers include the polyaryl ether ketones family, of which the polymer called poly ether ether ketone (PEEK) is the most widely used and recognized member. With 40 years of experience meeting the demands of other regulated markets, such as Medical Devices and Aerospace, Victrex understand the role that modern high performance polymers can play in helping regulated OEMs come up with new solutions. Over 50 quality checks per batch of polymer ensure quality and consistency lie at the heart of our materials solutions. For example, today the Victrex™ PEEK material is used in 200 million automobile braking systems, over 13 million medical implants and over 15,000 aircrafts.

The medical grade of PEEK (called PEEK-OPTIMA™) has been used instead of metal in load- bearing implanted medical devices, such as spinal fusion cages, due to properties including inertness, resistance to corrosion and degradation (through fatigue, wear or chemicals) and compatibility with imaging technologies (such as x-ray, MRI and CT). Many benefits of which are transferrable to the food industry.

Victrex have been supplying food contact materials into the Food equipment manufacturing industry for decades, but with the increasing compliance and performance needs of the market (eg. the FSMA), we have responded by creating a product family that especially meets the increasingly stringent regulatory and quality demands and helps remove the burden for equipment manufacturers. In addition, these materials can also offer customers new ways to be more cost effective, increase productivity and enhance performance.

INTRODUCING VICTREX FG™

The VICTREX FG™ (Food Grade) range meets the most stringent food contact material requirements (including safety, quality and regulatory compliance) of the industry (specific details available upon request) – to ensure that customers only taste what they are supposed to taste. The range of polymer solutions meet the testing criteria of industry governing bodies such as the FDA and EFSA for food contact and KTW and WRAS for water contact. The VICTREX FG™ range are a selection of engineered high performance polymers that have been created to specifically meet the most commonly required performance criteria for food contact materials – strength, toughness & wear resistance. The VICTREX FG™ series of Victrex™ PEEK products are in compliance with major regional food contact regulatory standards (specific details available upon request). Safe in the knowledge that the materials comply with the strictest regulatory requirements, the portfolio offers design freedom to product managers, designers, engineers and plant managers.

The VICTREX FG™ product range can also mean that manufacturers have an alternative for metal components, without having to produce the parts through milling. The VICTREX FG™ range can be used for precision injection moulding, which enable cost and time reductions through a single manufacturing step when producing parts in high numbers.

Figure 10. Bottling production line

CASE STUDIES

The environmental conditions that modern food contact materials must be able to resist include the handling of concentrated chemicals and their repetitive, prolonged use under more extreme conditions.

DISPENSERS - Ingredient formulations and intermediates are increasingly being used in concentrated forms, for dilution at a later stage. This allows storage and transportation costs to be lowered. Examples such as highly concentrated sugar-alternative sweeteners or flavors can present new challenges - since they expose traditional materials to completely new chemical formulations and gradients, which can reduce the material lifespan and performance. Beverage equipment manufacturers are using high performance polymers such as VICTREX FG™ for line storage vessels, provide pumping component and filling nozzles that can tolerate conditions that expose the materials of construction to high concentrations of chemicals, and must be stored over time for eventual mixing with a common diluent like carbonated water. VICTREX FG™ is highly chemical resistant and has been tested under stringent food contact requirements.

Figure 11. VICTREX FG™ Filling Nozzles

COFFEE MACHINES - Consumer demand for commercial and domestic coffee products is driving equipment development. In professional coffee machines, the pressure is on to ensure the optimum water quality for the perfect brew. Water quality and taste is influenced by materials of construction. The life of a coffee machine is an arduous one; steam, water, coffee, milk and cleaning fluids all conspire to undermine the integrity of materials and leach unwanted toxins into the beverage. For example, traditional brass and stainless steel are made up of alloys which include toxic metals lead and nickel, respectively. Under certain conditions, these alloys can be prone to metal leaching[11]. The growing concern on heavy metal contaminants is evidenced by the 2017 and 2020 revisions revision to EU 10/2011 reducing permissible migration limits for nickel levels to 0.02ppm, new specific migration limits for certain metals and an assessment of non-intentionally added substances (NIAS) in addition, the Council of Europe's addition of lead to the REACH Substances of Very High Concern (SVHC) candidate list, with a specific release limit of just 10ppb[11]. This could pose a serious consideration for health (in the case of the constituents nickel and lead), taste perception and end product quality[11-17]. VICTREX FG™ is an effective alternative for brass and stainless steel components, removing concern over heavy metal contamination.

Figure 12. Commercial coffee machine

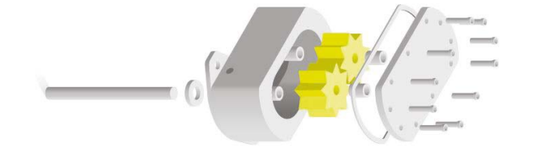

Figure 11. VICTREX FG™ Gears

BAKERY - Product differentiation and texture and taste experiences frequently mean that abrasive ingredients such as hard crystals, are present on the surface of foods, or are in suspension in a liquid. These can be more aggressive as they make contact with materials of construction. Selecting materials with enhanced wear resistance can remove some of the challenges associated with their use (such as frequent part replacement, downtime, loss of product quality or contamination). VICTREX FG™ has been used for cutting and stamping dies as a solution that has better abrasion resistance than other polymers and less product adhesion or wear debris contamination of metals.

PASTA - Exposure to high temperatures invariably occurs during the processing of food as the ingredients are cooked, preserved or dried. One manufacturer uses VICTREX™ PEEK in its range of food processing belts which are used in aggressive food cooking environments. Here, excellent wear, product release, mechanical properties and high temperature performance are required. The coated belts provide increased wear and abrasion resistance, improved cut-through resistance, increased puncture and impact resistance, as well as non-stick properties. When these properties are combined with improved dimensional stability, resistance to oils and grease, and continuous temperature resistance up to 260°C (500°F) the belt's life can be increased by up to 40%, reducing both downtime and maintenance costs of the line. Other manufacturers of short cut dried pasta have identified PEEK as a solution that can allow faster throughput of product. By switching the conveying belt material to a VICTREX™ high performance polymer, the belt material can tolerate an elevated drying temperature. This in turn enables drying times to be cut, which raises drier capacity significantly on a pasta processing line.

Figure 13. Pasta Manufacture

CONCLUSIONS

Modern materials have a role to play in helping equipment manufacturers meet the increasing demand from food companies. Adopting the next generation of materials, such as the VICTREX FG™ high performance polymers, mean that company executives can enable innovation within their organization and differentiation from the competition to grow revenues and market share. On a day-to-day basis, these materials can offer quick and easy integration through Regulatory and Quality compliance. These materials can increase performance through their customized properties that are tailored for wear, strength or toughness. The benefits of these materials being polymeric also mean that cost reducing technologies can be used for part manufacture. All-in-all the high performance polymers in the VICTREX FG™ range should be considered by all levels from executives to designers, engineers, quality and production managers as they seek to specify new equipment.

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