Identifying and Reducing Potential Risks of Contamination in Food Packaging

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Abstract

The purpose of this study was to identify the possible health hazards in food packaging and evaluate each component of food packaging for risks and potential improvements. There have been recent cases in which contaminants have been identified in various food packaging products that pose potential harm to consumers. National authorities, like the Food and Drug Administration and the European Food Standards Agency, regulate these contaminants and create regulations for industry standards.

Contaminants travel from food packaging to the food-surface through a process called migration. Migration varies depending on the usage of different substrates, inks, varnishes, and printing technologies. Each of these elements contains unique chemical characteristics which affect the amount of migration that occurs in packaging. As the food packaging industry is expanding, new contaminants are being introduced and toxicological tests need to be carried out to create migration thresholds and safer food packages.

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Chapter 1: Intro and Purpose of Study

One important part of maintaining a healthy diet is to look at the ingredients and nutritional information that make up foods. It is actually required by law, even at fast food restaurants, to include the ingredients and nutritional information so that people are not exposed to harmful substances in their food. These laws protect people from consuming unhealthy or unnatural foods. The reason that the United States Government enforces such laws is to ensure that the food sold in stores is not hazardous and can be trusted. It is for these same reasons, that there should be more attention paid to the packaging that our food is stored in.

There are many different forms of food packaging used in the United States today. For example, tuna and fruit cocktail can be stored in cans, turkey and butter can be stored in plastics, and candy bars can be sealed in thin foils with a branded design made of ink. There are many other substrates used to store and preserve food in grocery stores. Packaging for food has seen many innovations throughout time, incorporating new technologies, inks, and varnishes to create eye-catching printed graphics while preserving freshness and increasing the shelf life of food. These new methods of packaging have been beneficial in longevity, but they are potentially harmful to humans. In fact, new studies have shown that commonly used substrates and inks used for food packaging may contain harmful chemicals which can lead to cancer and other serious health problems. Buying these products could be a risk and an unpleasant surprise to consumers.

This study asks the question: Do commonly printed substrates and inks for food packaging contain harmful substances that pose health problems, and if so, what are the best possible methods to identify and eliminate these threats? It seems that food packaging could be

harmful to a person's health. If there are harmful substances present in food packaging, there might not be the necessary dosage to harm a healthy adult, but these substances could pose risks to infants or people who are already sick. Food packaging might be harmful, but the health threat has not been proven serious enough to encourage manufacturers to change their packaging methods or for consumers to stop buying packaged foods. There could be a risk in overlooking this packaging issue and it should be taken more seriously. Some of the possible health risks could even be life threatening.

The purpose of this study is to identify methods to detect the properties and chemicals of food packaging that could be harmful to human health and present strategies to reduce these threats. If in fact these substrates and inks pose a serious threat, they will need to be replaced by less harmful substitutes for food packaging. It is the responsibility of government to create awareness of different newly discovered health risks such as UV exposure and cigarette smoking, the next issue might just involve health risks from food packaging.

Chapter 2: Literature Review

The Food and Environment Agency (FERA) in the United Kingdom performed research on the migration of chemicals from packaging materials into food. They work closely with the printing industry on many different research projects that are funded by the UK government and other parts of Europe. FERA conducted research to spot and identify migrants in food contact substrate. The "staff are experts in policy and legislation in this area as well as in the analysis of these matrices. In addition the skills within the team have been applied to the development and validation of analytical methodology for a variety of food contaminants from other sources" (Potter). FERA's team used many advanced technologies to identify these contaminants in food and different types of substrates and food contact materials. According to FETA there are potentially tens of thousands of migrant chemicals that may be found in food and that plastics are the only substrate with European regulation currently.

FERA's team conducted a case study on the presence of the chemical 4-methylbenzophenone (4-MBP) in the paperboard of cereal boxes packaging. German authorities noticed a "migration of 4-MBP, a volatile component of the inks on breakfast cereal corrugaed boxes, into the cereal food" (Crossley). A risk assessment was conducted and reported concentrations in food up to 3.7 mg/kg. The team found that "based on the limited exposure data available and applying knowledge on the toxicity of a similar substance, benzophenone, FERA concludes that short term consumption of contaminated breakfast cereals should not pose a risk to most people. However, if the use of (4-MBP) is to be continued, more data on occurrence…as well as appropriate toxicity data corresponding to the level of exposure for a full risk

assessment" (Crossley). On March 6th of 2009, The Standing Committee on the Food Chain and Animal Health published a statement about 4-MBP that said, "Food contact materials printed with inks containing 4-MBP or Benzophenone should not be brought in contact with foods unless it is demonstrated in the company's in-house documentation that the transfer into food of the sum of 4-MBP and Benzophenone is below 0.6 mg/kg food" (Potter). This new proposed level of .6 mg/kg is more than six times less than the reported concentrations reported by FERA previously. This reveals the fact that there are chemicals in inks used for food packaging that have not been tested for safety and could be dangerous. Like in the case with 4-MBP, there are chemical contaminants which need to be tested for and limited (Crossley).

It is not only ink that is causing this contamination. FERA also conducted research on a high volume production chemical called Melamine. Melamine is a chemical that is used as a monomer and additive for plastics which is commonly used to make coatings, inks, and adhesives. Melamine gained notoriety in China in 2008 when it was added to infant formula milk. It was added to the formula to make it seem like more milk was present and it did not change the appearance. Of seventy-nine powdered infant formulas, twenty-two were affected with levels up to 4.7 mg/kg. At the time it was not known that Melamine was a harmful substance until 2009 after twenty-three million Chinese infants were screened, approximately 294,000 infants suffered some kind of adverse effects, predominantly renal tube blockages and kidney stones, and seven infants died. According to FERA's research, the limit of dietary exposure of Melamine is 0.013 mg/kg body weight per day, and their highest recorded level of melamine was 0.33 mg/kg found in the coatings for can and jar lids for food packaging. Also, Melamine can be found in melaware plastics. The migration from the melaware plastic to food is highly influenced by heat, such as being in the microwave. "The overall migrate can legally be

up to 60 mg/kg from plastics we know the starting substances, and additives. Different approaches to risk assessment and risk management must be considered" (Crossley).

Another concern for plastic substrates involves water bottles. "The type of container can dramatically affect the taste of the water inside. Lower grade plastics such as HDPE (high-density polyethylene, from which milk jugs are often made), can give a "plastic taste" to the water. It is advised to buy water bottles made with polyethylene terephthalate (PET) because it is considered the safest because it is a high-grade plastic. Yet, even PET can contain contaminants, which move into the water over time. (EHSO). It is advised to check for a number stamped on the bottom of plastic water bottles when you buy plastics. The safer plastics are labeled with a resin identification number between one (PET) and four. PET is a level one because "while most thermoplastics can, in principle, be recycled, PET bottle recycling is more practical than many other plastic applications," and can be used to make many new materials such as polar fleece and fiber for polyester products.

PET can also contain contaminants though. "A study conducted by researchers at the University of Heidelberg (Germany) Institute of Environmental Geochemistry tested for antimony in waters bottled in PET containers and found concentrations of more than 100 times the average level of antimony in uncontaminated groundwater, which is 2000 parts per billion (ppb). The concentrations of antimony increase the longer the water was stored in the plastic. "Antimony is a catalyst that is often used as antimony trioxide or antimony triacetate in the production of PET. After manufacturing, a detectable amount of antimony can be found on the surface of the product. This residue can be removed with washing. Antimony also remains in the material itself and can, thus, migrate out into food and drinks. Exposing PET to boiling or microwaving can increase the levels of antimony significantly, possibly above USEPA

maximum contamination levels. The drinking water limit in the USA for antimony is 6 parts per billion. The bottom line: choose glass or PET plastic, and then use it promptly" (EHSO).

Substrates are not the only point of concern when it comes to contamination of food packaging. It was not until 1994 when the Food and Drug Administration (FDA) noticed that lead was becoming prominent in candy products. "California authorities found that an imported candy product from Mexico was contaminated with lead that had migrated into the candy from lead-based ink used in the candy's packaging. The package was poorly designed such that its inner coating did not maintain its structural integrity, allowing lead-based ink in the outer package layer to migrate into the candy" (FDA). This form of contamination was a result of a weak paper substrate and a lead-based ink which was a possible contaminate. If the foil substrate were less permeable it would have prevented the hazardous ink from migrating to the food. "Subsequently, the FDA began testing other candy products with lead-based printing inks on their packaging to determine whether lead from the ink was migrating into the candy" (FDA).

In 1995 the FDA wrote a letter to manufacturers, importers, and distributors of imported candy and candy wrappers and started conducting studies to test lead as a possible contaminant. They found that "if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food... Finished packaging films are frequently distributed to end users (e.g., candy manufacturers) in rollstock form (i.e., rolled onto cores) in which the outside and food contact surfaces of the film are in contact" (Shank). This

means that even if a strong and safe substrate is used to package food, the package is considered unsafe if the ink used is lead-based.

In 1995 the FDA was not sure how much lead could be officially considered harmful and in turn did not establish a maximum threshold of lead in candy. The lead threat came to the FDA's attention was from products offered for import and products imported into the U.S. that use lead-based printing on candy wrappers and findings of lead in the candy itself. Lead levels can vary greatly depending on the contents of the candy itself. Candies that contain lesser refined ingredients than sugar may have higher levels of lead present. After some research, the FDA said "that sugar, the principal ingredient in most candies, when produced under good manufacturing practices, should contain levels of lead substantially below 0.005 ppb" (Shank). However, this level was a mere recommendation and was not enforced in any way as a toxic threshold.

More recently, in 2005, the FDA came out with a new recommended maximum level of lead in candy for small children. "This guidance provides a recommended maximum lead level of 0.1 ppm in candy likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy" (FDA). This enforcement policy still does not pose a legally enforceable limit, the level is just a recommendation, however they "have authority to take regulatory action against any food product that contains a poisonous or deleterious substance that may render the product injurious to individuals…our regulations require that equipment and utensils used in the production of food be designed and used in a manner that precludes contamination of the food with unsafe substances" (U.S. FDA). These utensils and equipment should include the packaging and ink because they are likely to come into contact with the food. Based on the research done by FERA and the FDA, it is clear that there are

harmful chemicals in our packaging that needs to be identified and controlled. There are many more to discover and it will take a very long time until they are all identified, but persistence, awareness, and health are the priorities.

Chapter 3: Research Methods

Packaging for food has changed over time. New strategies are constantly being discovered to increase the shelf life of food, attract buyers to the brand, and keep food fresh for customer satisfaction. At first glance, this seems like a good thing. New materials and chemicals are being integrated to improve the effectiveness of food packaging, but the downside could be an increased risk of exposure to hazardous chemicals. Potential health risks range from itchy eyes to cancer. The threat is real and seems to be overlooked. The purpose of this study is to identify the chemical properties of food packaging that could be harmful to human health. The types of research that will be used are historical research and content analysis.

The findings and data will be collected by historical research. When conducting historical research, "the historical researcher must systematically and objectively locate, evaluate, and interpret evidence available for understanding the past. From this evidence the researcher hopes to show what may be contributed by past experience to a greater understanding of present situations and what might happen in the future" (Levenson). Historical research will provide many case studies that have already been performed and recorded by professional teams and scientists that will provide several useful sources. The last research method that will be used is content analysis. "Content Analysis is a method for quantifying qualitative information gathered from historical research, and descriptive research." This type of research will summarize the findings about food packaging and food contamination based on numerical data. The most prevalent harmful properties and chemicals present in several different types of products will be identified and evaluated for safer alternatives. These research methods will result in a collection of data that can be analyzed and reported to answer the research question: Do commonly printed

substrates and inks for food packaging contain harmful substances that pose health problems, and if so, what are the best possible methods to identify and eliminate these threats?

The historical research will comprise of statistical findings posted either online or by scholarly journals and experiments. One of the organizations that posts reliable research findings online about food packaging issues is the U.S. Food and Drug Administration (FDA). "The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs…the FDA also enforces other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs. These include sanitation requirements on interstate travel and control of disease" (FDA). The FDA is responsible for monitoring all of the foods and food packaging that are sold in the United States to make sure that food products are safe, clean, and healthy. In order to monitor the levels of contaminants in different evolving substrates, the FDA has to continuously conduct research and perform experiments that they make public on their website. There have been experiments that have been conducted in the past that have shown harmful contaminants in new substrates and had to make new laws.

In 2007, the FDA published a guidance for the food packaging industry titled "Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations." The results contain non-binding recommendations of contaminant thresholds on a variety of substrates. The publication tested substrates ranging from cans to fatty foods to adhesives. "Recently, semi-empirical methods have been developed to determine migration levels using limited or no migration data. These diffusion models rely on estimation of diffusion coefficients based on the nature of the migrant and the physical properties of the

polymer. These models may be useful substitutes for, or additions to, experimental data under limited circumstances…First, distribution of the migrant in the polymer is considered isotropic. Non-isotropic distribution, whether intentional or unintentional, would be expected to result in non-Fickian migration. Second, other aspects of migration, such as partitioning, mass transfer, polymer morphology, shape/polarity of the migrant, and plasticization of the polymer are not considered in these models. These factors should be considered carefully when deriving migration levels to food using modeling techniques." These estimation coefficients are some of the only measuring tools that can predict migration levels accurately. It is an efficient method to estimate contamination levels so that standards may be set by the FDA (FDA). These contamination levels will be listed and used in the content analysis section.

In February of 2007 a journal called "Food Additives and Contaminants" was published. The focus of the journal was evaluating the migration models that would support legal regulations for plastic food packaging. "Recently, the European Commission charged an international group of experts to demonstrate that migration modeling can be regarded as a valid and reliable tool to calculate 'reasonable worst-case' migration rates from the most important food-contact plastics into the European Union official food stimulants." In other words, this group created a formula that could be used to calculate the migration rates in plastic substrates. "The paper summarizes the main steps followed to build up and validate a migration estimation model that can be used, for a series of plastic food-contact materials and migrants, for regulatory purposes…The successful accomplishment of the goals of this project is reflected by the fact that in Directive 2002/72/EC, the European Commission included the mathematical modeling as an alternative tool to determine migration rates for compliance purposes." There have been a lot of scientific research conducted in the past twenty years that have shown that migration from food-

contact materials such as plastic into food is a physical process that can be calculated through mathematics. Flick's laws of diffusion mathematically describe how a mass transfer between plastic contact-materials to food is possible (Begley).

Fick's first law of diffusion is "Whenever an impurity concentration gradient exists in a finite volume of a matrix substance (the silicon substrate in this context), the impurity material will have the natural tendency to move in order to distribute itself more evenly within the matrix and decrease the gradient. Fick's second law of diffusion states "that the change in impurity concentration over time is equal to the change in local diffusion flux" (Silicon Far East). "Hence, in addition to the experimental methods, a new alternative tool appears to be applicable which is based on theoretical migration estimations. Modeling of potential migration is already used by the FDA as an additional tool to assist in making regulatory decisions" (Begley). These laws will support the mathematical data from the experiment, and these findings will be recorded to see whether the contamination levels are dangerous enough to cause government regulation, and what are the properties that make this plastic a health hazard.

Another good source for historical and descriptive research is The Food and Environment Agency (FERA). FERA is a group in the United Kingdom that conducted research on chemical migration between packaging substrates and food. FERA conducted extensive research to find the contaminants that are migrating to the food through various substrates (Food). Like the FDA, FERA makes sure that food packaging is safe for the public. The "staff are experts in policy and legislation in this area as well as in the analysis of these matrices. In addition the skills within the team have been applied to the development and validation of analytical methodology for a variety of food contaminants from other sources" (Potter). In this study, FERA focuses on non intentionally added substances. "for melamine (and BPA) the migration comes not just from the

classical (diffusion) but from degradation of the plastic – to form known substances. In most other cases new and/or unknown substances can be released." Melamine is a chemical that is used as a monomer and additive for plastics which is commonly used to make coatings, inks, and adhesives. This migration from non-intentionally added substances can result from impurities in the substances from the beginning, degrading substances, reaction products, and oligomers. These results will be helpful in drawing conclusions about ink contaminations that may not be intentional food contamination (Potter).

Content analysis will be conducted by finding the recommended threshold of different contaminants listed by the FDA. Each element of food packaging, including substrates, inks, varnishes, and innovative printing technologies, will be broken down by their characteristics and evaluated for improvements. By combing all of the data, a proposed strategy will be composed with the goal to improve methods of identification and reduction of contaminants in food packaging.

Chapter 4: Results

In order to identify and regulate the migration of contaminants into food, data must be collected and recorded from toxicological research. In the United States, “direct food additives are not naturally considered a component of the food, but they are approved by the Food and Drug Administration (FDA) if the addition performs a specific function. Indirect food additives are not however, because there is no intent of functionality. Instead they are expected to migrate into the food and are converted into potential indirect food additives that are regulated.” In Europe, the rules are more specific. They have established that “materials and articles intended to come into contact with foodstuffs provides the basis for the assurance of a high level of protection of human health and of consumers’ interests in relation to food packaging, whether printed or not” (ESFA). The application of printed inks on the food-contact side or the printed surface of food packaging must not allow substances to transfer to the food-contact side and the printed surfaces.

Despite the differences of regulatory practices regarding food packaging, the FDA and European Food Standards Agency (EFSA) share similar regulation in that there is “no use of migration of carcinogenic, mutagenic, or reprotoxic substances (CMR subs), the level of migration of even physiologically non-objectionable substances must remain below defined concentration limits, there must be no change in the color of the foodstuff, there must be no change in the odor or tastes of the foodstuff, and there must be no adulteration of the foodstuff” (Customer Guidance). These laws and thresholds are continuously being tested and updated as technology grows and methods of monitoring contaminants are being improved.

In America, it is the responsibility of the Food and Drug Administration (FDA) to ensure that food packaging products are safe and effective. “Premarket approval by the FDA is currently required for food packaging materials used in the US that are not GRAS (Generally Required As Safe), prior sanctioned, or not reasonably expected become a component of food. In some food packaging applications the amount of migration could be considered so small as to be negligible and therefore present no public health or safety concern. In an effort to improve and speed the food additive petition process, the FDA has adopted a threshold policy that defines this negligible exposure from migration” (Begley). Thresholds considerations include a substance’s dietary concentration and its toxic potency. “The toxic effects from ingesting chemical substances occur in predictable dietary concentration ranges by studying migration, so the FDA established a “0.5 µg / kg dietary concentration as the threshold of regulation” (FDA).

In Europe, the ESFA is performing similar toxicological evaluations. The ESFA, like the FDA, conducts tests and collects comprehensive data focusing on the toxicity of food contamination through the process of Migration (ESFA). They “required the industry to obtain approval of these substances which are used and are present in food packaging. This approval process is also required when there is an intention for use of any new substances. In order to be approved, comprehensive toxicological data has to be compiled for each new substance” (Customer Guidance). Once the data is compiled, the ESFA uses it to create industry thresholds with a goal to reduce the migration of food contaminants. “Thus these ‘positive lists’ provide the data for acceptable transfers into food for each individual substance,” also known as the Specific Migration Limit (SML). These tested substances are also known as “Evaluated Substances”. If the substances that are listed with a SML are present in additions such as inks, varnishes, or

adhesives, then the entire package must be within the specified limitation. This grand total of contaminants is known as the Overall Migration Limit (OML) (Customer Guidance).

In order to measure the Overall Migration Limit, toxicologists use simulation migration tests. “Sponsors should provide information sufficient to permit estimation of the daily dietary concentration of the food contact substances (FCS), (i.e. consumer exposure). The FDA will calculate the concentration of the FCS or other components that might migrate to food expected in the daily diet based on analyzed or estimated levels in food or food simulants” (FDA). Food simulants are used for migration tests because using real foods would not be practical or cost-effective. The FDA classifies food simulants into four foodstuff categories depending on their characteristics and assigns them recommend stimulants for testing. The categories include aqueous, acidic, alcoholic or fatty food types. Aqueous and acidic foods use a simulants comprised of 10% ethanol, alcoholic foods use 10 or 50% ethanol, and fatty foods use food oil or corn oil (FDA). “Traditionally, migration tests are performed by using food-simulating liquids such as water, edible oils, ethanol/water solutions and sometimes food. These tests are time consuming in two ways; generally the accelerated tests run for at least 10 days and the analysis of the migrants at low concentrations in the stimulants or food is generally difficult. These analyses are also expensive and generate hazardous laboratory waste in an effort to overcome the inherent difficulties associated with migration testing and possibly simplify the process by which FDA evaluates migration from food packaging. Predictive migration modeling offers advantages” (Begley). The predictive migration method is a shortcut to simulation testing which will be explained in the following chapter.

Of the three types of migration, the most relative to printing is known as visible set-off. “Set-off is the unintentional transfer of substances used in printing from the external printed

surface of food packaging to the inner, food-contact surface" (Bentayeb). "It can occur when the packaging is produced and stored in stacks or reels after being printed. The quantity of ink components transferred depends on the type of ink, the drying/curing procedure, the time of contact, and the pressure in the roll or stack of sheets. Set-off is the main mechanism whereby the food could become contaminated by high molecular weight substances" (Bentayeb). The amount of set-off varies relative to the type of substrate, ink, and varnish used in the package so it is important for manufacturers choose their materials accordingly.

Choosing a substrate is the first important element to consider when creating a safe food packaging product. More migrants diffuse in substrates with higher contact surface and lower volume/weight, longer shelf lives, and exposure to heat. Barrier properties determine the strength of resistance that a substrate has to the potential migration of harmful contaminants. Substrates with poor barrier properties between the ink and food allow more migrants to diffuse quicker. Some poor barriers include coated paper, uncoated paper, coated board, uncoated corrugated board, regenerated polypropylene, adhesive layers, printing varnishes, and lacquer coating layers. Substrates with slightly stronger, but still limited barrier properties consist of polyamide, polyethyleneterephthalate, polyvinylidene chloride, metallization, and polypropylene layers. The layers recognized as functional barriers are aluminum foil, tinplate, glass, and sufficiently thick layers consisting of polyethyleneterephthalate or polyvinylidenechloride (Customer Guidance).

Substrates influence the amount of visible set-off which affects the migration levels. Visible set-off has presented issues on substrates such as corrugated boards stored in stacks, in paper sugar packaging, and plastic yogurt cups. In retail food packaging, if set-off is detected in the retail food packaging, all of the affected product will be recalled, so rapid detection is important. With so much at risk, it is vital that manufacturers understand the chemical properties

of both the substrate and the type of ink that they are using because various inks react differently depending on the substrate they react with. For instance, “paper, board, and corrugated board do not act as adequate barriers to migration-capable constituents of ultra-violate curing printing inks and varnishes” (NewV). UV ink is a relatively new option for food packaging so manufacturers need stay aware of migration characteristics in order to produce safe products with migration levels within the established threshold.

The use of Ultra-Violate (UV) inks has been a growing trend in food packaging. “As UV flexo inks have a high potential for technical development many formulations are new, and require safety regulation authorities to undertake stringent procedures and undertake expensive testing to reassure the costumer’s health. On the other hand, established solvent and water-based ink formulations are less often under such scrutiny due to a slower drive to innovate, at the same time reducing overall ink costs against UV inks” (Federico). In recent history, there has been a lot of uncertainty within the guidelines and regulation of UV inks because it is a relatively young industry product. The ESFA has assigned “non-evaluated” inks a threshold of 10 ppb. Many UV curing inks surpass this threshold because they have low molecular photoinitiator migrants. “UV inks dry in the press by means of a chemical reaction in the UV curing unit where low-molecular photoinitiators and vehicle molecules are cross-linked to build a polymeric, solid film” (NewV). There is a potential for migration when conventional UV inks and varnishes cure. “This contamination is often enhanced by insufficient drying of the ink caused by high printing speeds, aged UV radiation lamps, high ink density, long time in reel or stack, high pressure in reel or stack, and storage above ambient temperatures” (Customer Guidance). However, UV inks are becoming more favorable with the introduction of innovative curing methods.

The first new method of UV curing is Cationic Polymerization, which was introduced because it offers new unique properties; it is sensitive to moisture and alkaline water-based inks and uses free radical polymerization of acrylate materials that don't stop until full polymerization is achieved. This eliminates the concern of UV acrylate systems in food packaging because migration diminishes as polymerization is accomplished. Furthermore, this method decreases the amount of drying time that UV inks typically require (UV& EB). The second innovative method of UV curing is called Electronic Beam (EB) curing. EB curing "would eliminate the concerns about heat, eliminate the need for photoinitiators, allow for the 'complete' cure of thick-ink films and minimize energy needs." EB curing has all the benefits of UV, but it reduces negative side effects such as heat management, odor, off-taste, and most importantly migration of food contaminants (UV& EB).

Another way in which migration can be kept to a minimum in flexography is by using a solvent-less laminator. When a solvent-less laminator is used, "the packaging web is printed, then a transparent film layer is laminated on top of the printed surface before rewinding the reel. The additional film layer acts as a protection layer, trapping the ink inside two layers: the printed web and the laminated web. The ink does not come into contact with the inside of the web while rewinding so no set-off ink migration is possible, and the ink cannot later come in contact with any food as it is trapped in the sandwich of the two layers" (Federico). This innovative technique of using transparent film laminations essentially eliminates any UV set-off migration in flexography.

The FDA and ESFA have a lot of different factors to monitor to reduce food contamination and create thresholds. It is important that manufacturers understands and examines every step of the process including selecting substrates, inks, varnishes, curing

methods, and overall levels of migration in order to create a final product that is within the specified migration threshold.

Chapter 5: Conclusions

Food packaging will never be considered safe or unsafe because it is constantly evolving with the industry. New innovative substrates, inks, varnishes, and printing techniques are constantly being introduced into food packaging, and each has component of food packaging contains unique chemical properties which vary depending on the way that they are mixed together. These unknown substances make up the category referred to before as “non-evaluated” substances, which are defined as “all substances which are used in printing ink formulations but which are not officially approved by a national authority and thus included in regulations and guidelines.” There needs to be more migration tests and public data in order to reduce the amount of “non-evaluated” substances. More data results in more authoritative conditions which would reduce the risk of food contamination in food packaging (Customer Guidance).

Currently, formal methods of migration testing use simulants and are time consuming, expensive, and create unnecessary hazardous laboratory waste (Begley). There are too many inks and substrates to conduct simulative migration test for every single type in a reasonable amount of time. Instead, authoritative groups, such as the FDA and ESFA, should save time and increase the productivity of verifying new substances by implementing the Predictive Method of calculating thresholds into law-binding industry standards. “For many packaging components, the amount of migration data available today and the ability to predict the diffusion coefficient of an additive/contaminant in the polymer make it possible to estimate the amounts of chemicals migrating from food packaging without the need for additional migration testing. Using approaches for conservatively estimating diffusion coefficients and migration amounts will ensure that migration amounts are not underestimated” (Begley). The Prediction Method is based

on a discovery from the 1970s, when a scientist named “K. Figge studied the migration of antioxidants from HDPE, PVC and PS into food oils and fat simulants. These studies proved “that the migration to the oils and fat simulants was predictable.” From this study, it was discovered that “the amount of migration is controlled by diffusion through the polymer and diffusion follows Arrhenius type behavior” (Begley). The results revealed that the amount of migration to the food-surface can be calculated in a mathematical equation, and it will always be less than the food simulant that is used for simulation testing to ensure safe thresholds (Customer Guidance).

The FDA and ESFA uses a similar approach of predicting migration for “non-evaluated” substances, but the mathematical approach used by the Predictive Method has not yet been used for legal regulation by either authoritative group. Instead, the FDA keeps track of these predicted measurements in a “migration database, intended as a resource for migration data, including diffusion coefficients and relevant polymer/additive properties. The FDA continues to compile migration data from various sources for use in estimating migration levels for FCSs. Reliable migration data (e.g. data that follow Fickian diffusion), provided in support of a premarket submission for a food contact substance would be added to the database” (FDA). The ESFA established a threshold of 10 ug/kg for these “non-evaluated” substances, but like the FDA, European Legislators still consider “non-evaluated” substances to be unsafe because there is such a small amount of toxicological data made available. Currently there is no formal migration testing performed by authority toxicologists (Customer Guidance). The Predictive Method would be a beneficial replacement for simulative studies because they create realistic estimates of migration and exposure which are time-efficient and accurate.

To ensure the safety of food packaging there needs to be more formal testing and collaboration between manufacturers, research groups, and federal agencies. Ink and packaging manufacturers need to recognize their responsibility to work together to ensure that the safest food packaging products are created. While “ink manufacturers can certify the suitability of an ink series for food packaging applications, they cannot, however, certify the legal compliance of the final printed packaging. The reason is that many parameters have an influence on this compliance, such as the substrate used, the printing and converting process, and the storage conditions at all stages. In order to avoid any problems arising from an improper use of ink, it is important that all parties involved in the printing and packaging process collaborate” (Customer Guidance). This collaboration between manufacturers creates more accountability to match safety standards. Research groups and national agencies need to continue conducting migration tests, post their findings publicly, and collaborate within the international food packaging industry. The FDA made a big step in this direction on May 5, 2011 when they passed new regulation which “requires anyone importing food or animal feed into the United States to tell the FDA if any country has blocked importation of the same product. This requirement will give the agency more information about imported foods, improving its ability to target foods that may be hazardous” (FDA). This regulation will keep unhealthy imports from being distributed in America and will provide insight about new potential contaminants that other countries have identified. Every country should implement a policy like this one.

The future holds new innovative technologies that will counteract migration and the negative side-effects of food contamination. There have already been improvements made to the usage of UV inks in food packaging. Researchers have developed new strategies of curing using cationic polymerization which decreases the amount of visible set-off during drying for UV inks

by using free radical polymerization of acrylate which continuously works until full polymerization is reached (UV& EB). Another innovative method of reducing set-off migration is by “reducing the use of solvents, using ultraviolet light or electron beams to polymerize prints, applying a clear varnish to protect the printed surface, and using anti-set-off powders to reduce the friction in stacks and rolls” (Bentayeb). These stacks are then visually inspected under specialized UV lamps used for detecting non-visible set-off.

In addition to curing methods, there are new methods to eliminate set-off with solvent-less laminating machines for flexographic or gravure printing machines. “A majority of food packaging applications are printed on CI flexographic or gravure printing machines, where the reel of packaging is printed and then taken to an off-line solvent-less laminating machine. The solvent-less laminator applies to the surface of the printed substrate (or vice-versa) a second layer of an alternative substrate to add high-gloss, scuff-tear resistance, protection from ink contamination, plus other mechanical and functional properties to the final packaging.” Solvent-less lamination is known to be the “predominant packaging laminating technology due its good bonding properties, no VOCs, reduced set-up waste, reduced capital investment cost, single operator operation, low energy consumption and flexibility to laminate most of the available packaging substrates” (Federico). Because there are so many new issues involving migration levels in food packaging, the market for such innovative printing products is on the rise.

Most of the substrates and inks that are commonly used in food packaging do in fact contain harmful substances which could be harmful to human health, but the amount of migration that takes place does not impose immediate health risks when “evaluated” substances are used and the food packaging is tested for migration as a whole, including factors such as the types of substrates, inks, varnishes used. Without collaboration, the implications for consumers

could result in contamination related food-illnesses, and implications for manufacturers could result in unsafe products, and potential lawsuits. It has been seen “in many cases, responsibilities were not consequently perceived despite explicit legal regulations, that communication between all parties involved is dramatically lacking and needs substantial improvement and that parties involved are not aware of the consequences of changes in the “packaging system” and their respective impact on possible substance transfers into food (lack of a “change management” awareness), of the consequences of changes in the ‘packaging system’ and their respective impact on possible substance transfers into food” (Customer Guidance). The food packaging industry is still evolving and new chemical contaminants are constantly being introduced into products containing various substrates and inks. In order to effectively reduce the amount of migration of contaminants into food packaging, authoritative groups need to legally implement migration thresholds based on the Predictive Method of migration testing to increase the supervision of contaminants in food packages. The combination of increasing the amount of migration testing, posting public toxicological data, collaborating within the industry, and innovating technologies to limit migration is the best strategy to keeping food packaging as safe as possible for consumers.

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