HEALTH IMPLICATIONS OF FOOD PACKAGING

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INTRODUCTION

Ask educated consumers about the principal sources of food contamination and they are likely to list micro-organisms such as *E. coli* O157:H7 first, then agrochemicals, then environmental chemicals such as PCBs, hormones used for animal production, BSE/vCJD, and food additives. Chances are that few would mention food packaging materials, despite a recent review [Grob et al. 2006] suggesting that the amount of material migrating from food packaging into food may well be 100 times higher than that from pesticides or environmental pollutants.

Many of the public perceptions about food safety are skilfully manipulated and exploited by food marketeers. Fear of food contamination has led to a widespread preference for what are seen as ‘natural’ processes as evidenced by the growth of organic agriculture (20% annual increase over the last decade), and the increasing preference for bottled water as a beverage of choice. In fact bottled water has become a fashion accessory for many consumers in the mistaken belief that municipal water supplies are unhealthy. Although the global recall of bottled Perrier water in 1990 due to the presence of trace levels (12-19 parts per billion) of benzene resulted in a temporary decline of bottled water sales, their growth has been prolific. The recent admission by Pepsi that its Aquafina brand of bottled water is from a public water supply (i.e. tap water) will probably only result in a short-term dip in sales. Bottled water has become a talisman as a recent editorial in the British Medical Journal suggested [Petrie & Wessely 2004]:

“Bottled water is seen as a natural antidote to what the consumer sees wrong with modernity and bad for their health—chemicals and technologies full of risk and hazard, genetically engineered food, low level radiation, harmful medications, and sinister viruses”.

In this presentation I want to focus on components of packaging materials that have migrated into foods (so-called food contact substances or FCSs) and try and answer the question: should we as consumers be concerned about the health implications of these contaminants in our food?

In the time available it is not possible to mention all the many migrants from food contact materials and therefore a selection will be made based on those that have achieved some notoriety in the public domain.

Most of the migrants are present at very low levels such as mg/kg (parts per million or ppm), µg/kg (parts per billion or ppb) or even ng/kg (parts per trillion or ppt). The
following analogies may help in understanding the magnitude of such low concentrations:

- one ppt is equal to one grain of wheat in 100,000 tons. 100 trains each with 25 wagons are needed to transport 100,000 tons of wheat.
- one ppt is equal to 0.4 mm (the thickness of a credit card) of the total distance from the Earth to the Moon.
- one ppt is equivalent to 1 second in 31,797 years.

The public wants evidence of no risks, but all regulators can ever offer is no evidence of risk or evidence of a very small risk. The situation is complex because experts and non-experts can perceive the same risk in vastly different ways. Media claims of high levels of contamination or emissions are encouraged by large numbers attached to small units. For example, while 0.1 ppm sounds very low, half this level (50 ppb) sounds significant to many members of the public [Robertson 2006a]. However, regardless of the units used and the analogies made, increasing numbers of consumers want zero concentration of contaminants from the package in their food. But compared to other risky activities such as parachuting, risks related to food packaging are unique; food packaging-related risks can only be by-passed or avoided to a limited extent, especially for staple foods.

**THE CHANGING NATURE OF RISK**

What is the nature of the risk arising from food packaging and in particular food contact materials, and is it changing? While there have been tremendous advances over the past 20 years in the precision by which chemicals can be detected in foods and packaging materials, there has not been a concomitant increase in the public’s ability to appreciate just how small these concentrations are or understand the significance (or more correctly the insignificance) of extremely low concentrations of such chemicals in their foods.

In most developed countries, industry and regulatory authorities routinely measure at least some of the undesirable impurities that are in the food and declare the food to be pure when such impurities are not present, or if present, are below a regulatory-specified quantity or threshold. This raises the important issue of what is ‘zero’. How low should detection limits go to determine whether those impurities are, in fact, present? With each decade, analysts keep approaching a ‘smaller zero’ and zero keeps pushing back.

Therefore, as DeVries [2006] has pointed out, there is a need to consider how and when this zero level is chased. When a contaminant is found in food and deemed to be unacceptable, zero is set at whatever constitutes the current limit of detection (LOD) at that point in time. When an instrumentation manufacturer introduces a new analytical instrument this often results in a significant drop in the LOD, and with the lower detection, more and more compounds are inevitably detected. Therefore, the contaminant may be found to be present again at lower levels, and new contaminants may be detected for the first time.

This is a challenge to industry and regulatory authorities. As more compounds are found and reported on, society as a whole, because they have heard bad things about some of
these compounds, feels obligated to chase that receding zero despite the fact that the risk level was considered and regulations set based on data using the previous, higher detection limit [DeVries *ibid.*]. Can science draw a line at what should be looked at in terms of risk and how to set appropriate limits for these compounds? Should regulators be chasing zero in all cases? What detection levels should be aimed for in order to better define the risk to public health posed by these chemical contaminants and thus develop appropriate public health policies?

As zero is approached, anxiety is generated because more and more compounds are found, but since these additional compounds are detected at lower and lower levels, how much of a food safety hazard do they pose to human health? Dose makes the poison but at these extremely low levels, there is also a lot less risk. So how concerned should regulatory authorities be, and how do they allocate limited resources to pursue all of the possible issues raised when zero is approached? There is a need to draw some lines and apply best technology.

So has the nature of the risk changed? It has, firstly to the extent that foods and food packaging materials are sourced globally and details of the country of origin and/or method of manufacture are often non-existent or difficult to verify. Thus there is the possibility that a food contact material that is not approved for food contact use may be used either knowingly or unknowingly by a food manufacturer. The onus is placed on food manufacturers and retailers to ensure that their products are safe and that they comply with all relevant legislation. However, given the prohibitive costs of testing for chemicals in foods (typically up to $2500 per analysis for trace contaminants) and the unlikelihood of detection by any regulatory authority, food manufacturers rely on a written warranty in the form of a statement on compliance to food contact regulations from their packaging supplier. Perhaps random inspection and verification of such warranties by regulatory authorities would encourage their more widespread adoption.

**METAL PACKAGING**

When tinplate was first used to make containers for food over 180 years ago, many cases of food poisoning, apparently due to ingestion of excessive amounts of metal, occurred. A congress of physicians held in Heidelberg in Germany even went so far as to recommend that ‘tinplate should be forbidden for the making of vessels in which articles of food are to be preserved’. The quality of tinplate has greatly improved since those days, and foods which are likely to attack tin are packaged in tinplate containers with an appropriate enamel or lacquer coating [Robertson 2006b]. However, these enamel coatings are not as benign as you might think as discussed below.

**Enamel Coatings & Bisphenol A**

Bisphenol A is a known environmental estrogen that is used as the monomer to manufacture polycarbonate plastics and epoxy resins to line food cans. These thermosetting resins are obtained by condensation of bisphenol A and epichlorohydrin which yields bisphenol A diglycidyl ethers (BADGEs). Powder formulations of high MW
Epoxies are used mainly to coat the internal surfaces of two piece food cans, while UV-curable coatings are used to coat the exterior and ends of cans. The success of epoxies as coatings for food cans is due to their desirable flavour-retaining characteristics, their excellent chemical resistance and their outstanding mechanical properties.

In the 1990s high amounts of BADGE were discovered in fish in oil in tinplate cans. The US FDA and the SCF in Europe began investigating human exposure to bisphenol A and BADGE in order to ascertain whether the use of certain epoxy resins might be exposing consumers to estrogenic xenobiotics. The FDA concluded that there is no public health concern regarding these chemicals. However, a recent paper [von Saal & Hughes 2005] which concluded that widespread exposure to BPA poses a threat to human health directly contradicts several recent reports from individuals or groups associated with or funded by chemical corporations. The authors quote a report by the Harvard Center for Risk Analysis and funded by the American Plastics Council which concluded that evidence for low dose effects is weak based on a review of 19 studies; the authors found 115 studies of which 94 reported significant effects and called for a new risk assessment for BPA. In January 2007 the European Food Safety Authority established a full TDI of 0.05 mg/kg body weight, confirming the temporary TDI set in 2002.

**Lead**

The toxicity of lead, especially to the neonate, is a matter of great concern to regulatory authorities, as evidenced by the recent recall of toys decorated with lead-based paints, and the reduction last November by the FDA of the recommended maximum lead level in candy (arising from the use of lead-based printing inks) from 0.5 ppm to 0.1 ppm. Abundant evidence supports the fact that during early life, human infants are particularly susceptible to lead exposure, with a greater portion of the retained lead being distributed to bone and brain in infants than in adults. Subacute ingestion of lead by children results in encephalopathy, convulsions and mental retardation.

For many years the side seams of three-piece tinplate cans were soldered with a lead/tin (98:2) solder, resulting in some lead being taken up by the food depending on the amount of solder exposed to the food and the acidity of the food. To obtain the lower lead levels in baby foods it was common to use a pure tin solder which was considerably more expensive than the conventional solder. The newer welded cans have eliminated solder altogether and done much to reduce the lead intake from canned foods, typically to about one tenth (lead is a natural contaminant of tin as the elements coexist in the ore).

The tin/lead capsules used on wine bottles are produced by bonding extremely thin tin foil on both faces of a lead strip, the tin acting as a barrier layer and preventing contact between the lead and the wine. However, analysis of wine poured from bottles fitted with tin/lead capsules revealed the occurrence of toxicologically unacceptable concentrations of lead in 3 to 4 percent of wines tested. The use of tin/lead capsules has been phased out but older bottles with the foils may still be around.
Recent analysis of wines has revealed levels of lead ranging from 40 to 453 ppb, the wines having the highest lead contents being 40 year old ports. EC regulation 466/2001 limits lead in wine to 200 ppb, making the sale of many wines (especially ports) illegal if these recent analyses are typical. Lead migration from glass decanters into alcoholic beverages is another source of contamination.

**Antimony**

Antimony is a potentially toxic trace element with no known physiological function. Many consumers would be surprised to know that it has been detected in food and drinks packaged in PET. This is because antimony trioxide is used both as an additive and a catalyst in the manufacture of PET at a maximum level of 0.035%. The WHO drinking water group proposed a tolerable daily intake (TDI) of 0.36 mg Sb/person/day (360 ppb) and a drinking water limit of 20 ppb. The US EPA and Health Canada recommend 6 ppb for antimony in drinking water; Japan recommends 2 ppb.

A background level of antimony in pristine ground water in Canada is around 2 ppt, but once filled into PET bottles, these levels rise to around 50 ppt in 37 days and 566 ppt after 6 months storage at room temperature. German brands of water in PET bottles contained up to 626 ppt [Shotyk et al. 2006]. Very recently antimony residues in ready-to-eat meals heated in PET trays of up to 38 ppb were reported which is the SML [Haldimann et al. 2007]. About half of the products prepared in PET oven bags at a temperature of 180ºC exceeded the SML set by the EC. However, the migrated amounts of antimony relative to the accepted TDI give no cause for toxicological concern.

So what does this mean for consumers who want to reduce their intake of toxic metals? First, avoid metal cans with soldered side seams. Don’t drink old bottles of wine and port with lead capsules and don’t decant alcoholic drinks into glass decanters and store them for a long time. If you’re a big consumer of beverages packaged in PET bottles, don’t let them sit around for months before consumption. And if you consume a lot of ready-to-eat meals in PET trays, it may be worthwhile not reheating them in the PET tray. Also don’t use oven bags every day of the week.

**GLASS**

By now you are probably wishing that industry never switched from the glass bottle to PET. While it is true that no toxic chemicals migrate from glass into food, there have been problems with the closures used to seal glass jars, specifically the gaskets inside the metal lids.

**Epoxidised Soybean Oil (ESBO)**

A widely publicised food contact material incident in 1998 concerned the migration of epoxidised soybean oil (ESBO) and ESBO-derivatives from baby foods packed in glass jars with metal closures, the amounts sometimes exceeding the TDI. ESBO is used as a plasticiser and HCl scavenger in polyvinyl chloride (PVC) films and the gaskets of metal...
closures used to seal glass jars and bottles where it can be present at levels of up to 40%. ESBO is also used as a stabiliser in plasticised PVC cling films. The estimated exposure of infants aged 6-12 months to ESBO migrating into baby foods can sometimes exceed the TDI by up to 4- to 5-fold. A SML of 30 ppm for ESBO in baby foods has been in effect in the EU since November 2006; for other foods a SML of 60 ppm applies. ESBO migration into food containing free oil in contact with the gasket has been reported with a mean of 166 ppm in 86 samples and a maximum of 580 ppm [Fankhauser-Noti et al. 2005].

**Semicarbazide (SEM)**

Another baby food scare made the headlines in mid-2003 when semicarbazide (SEM) was detected in baby foods at levels up to 25 ppb. SEM is produced during the heat treatment of an approved blowing agent (azodicarbonamide which acts by releasing nitrogen gas) used in the manufacture of sealing gaskets in the PT (press on-twist off) closures of glass jars. The use of azodicarbonamide in food contact materials was banned in the EU from August 2005. SEM is in the chemical class of hydrazines, some of which are known to be genotoxic and carcinogenic.

A Canadian risk-benefit analysis of the use of azodicarbonamide in baby food closures funded in part by Heinz [Nestmann et al. 2005] concluded that the margin of safety is more than 21,000 and that any theoretical risk is outweighed by the benefits of continuing use of the PT closure (with azodicarbonamide blowing agent) to ensure both the microbial integrity and availability of commercial baby foods as a valuable source of infant nutrition. The analysis was published too late to influence regulatory authorities who had already committed to banning azodicarbonamide. It is the only example I know of an attempt to put the risk from trace quantities of food contaminants into perspective.

Incidentally, azodicarbonamide is an approved dough conditioner and levels of SEM in commercial bread products have been reported in the range 10-1200 ppb [Noonan et al. 2005]. SEM is also a metabolite of the banned veterinary drug nitrofurazone which has been found in exports of seafood, honey, etc. from some Asian and South American countries. However, SEM can also be formed from natural constituents in food such as creatine and arginine due to hypochlorite treatment and therefore its presence cannot be said to be unambiguously from nitrofurazone abuse [Hoenicke et al. 2004].

Recently a wine writer in New Zealand suggested that screw caps which have replaced traditional cork closures on many New World wines released estrogenic compounds into the wines [Stewart 2007]. The oxygen barrier material in screw caps is a copolymer of PVC and polyvinylidene chloride (PvDC) and it was argued that estrogenic compounds could migrate into the wine. The evidence for this claim was in an unpublished PhD thesis from The Netherlands where several nonyl phenol isomers were detected in one bottle of South African wine sealed with a screw cap; no details were given about the age of the wine. However, given the extremely small surface area of the cap liner relative to the volume of the wine, any migration is likely to be insignificant.
PLASTICS

A tremendous range and variety of chemicals are used to make modern packaging materials. For example, the European inventory list of chemicals used to make plastics intended for food contact numbers more than 1500 listed substances, and inventory lists of a similar length exist for chemicals used to make paper, can coatings, inks and adhesives. In this presentation I will only focus on some plasticizers used in plastic packaging.

**Endocrine Disruptors**

Surveys carried out in a number of countries have indicated that over the last few decades there has been a fall in the quantity and quality of male sperm, although the effects appear to be variable. There is also evidence that in some countries there has been an increase in testicular cancer. Much of the concern focuses on man-made – and mainly organic - chemicals as highlighted in the book *Our Stolen Future* by Colborn, Dumansky & Myers published in 1997. Endocrine disruptors are chemicals that enter the body from the external environment and mimic or interfere with the human endocrine system. Chemicals which mimic the female hormone estrogen or act as antiestrogens are suggested as being responsible for some observed effects on wildlife such as the feminization of fish. It has been further suggested that these same chemicals may be responsible for the above-mentioned male human health problems.

**Phthalates**

Phthalates are among the chemicals that have been labeled as xenoestrogens. Of the phthalic acid esters, di-2-ethylhexyl phthalate (DEHP) (also known as dioctyl phthalate (DOP)) is the most widely used. DEHP, together with DEP (diethyl phthalate) and DIOP (di-isooctyl phthalate) have been granted prior sanction by the FDA as plasticizers in the manufacture of food packaging materials for food of high water content only. Other phthalate esters have been cleared as plasticizers for various food contact uses. Rigid PVC packaging materials are unplasticized. Minor uses of phthalates in food packaging include use as plasticizers in cap liners made from PVC plastisols (ESBO is more common).

Plasticizers are commonly used in printing inks where they assist adhesion of the ink to the packaging material and improve the ink’s flexibility. A survey [Nerin 1993] of printing inks on a selection of packaging materials for products including confectionery, snacks, chips, potatoes, chocolate bars and biscuits in Spain and England found a number of plasticizers, with phthalates being the major ones. Although the inks were generally applied to the outer surface of the packaging materials and therefore were not in direct contact with the food, it has been shown that they can migrate through plastic layers to the food.

Thin plastic films known as ‘cling film’ are widely used in the home for packaging foods, and many (but not all) were made from PVC plasticized with DEHA. A UK survey of
DEHA levels in retail foods packaged in plasticized PVC found levels ranging from 1.0-72.8 ppm in uncooked meat and poultry; 9.4-48.6 ppm in cooked chicken portions; 27.8-135.0 ppm in cheese, <2.0 ppm in fruit and vegetables, and 11-212 ppm in baked goods and sandwiches. The level of DEHA migration correlated with the extent of contact between the film and exposed fatty portions of the food. More recent surveys have confirmed that phthalates are no longer used in the manufacture of cling films since linear low density polyethylene (LLDPE) has replaced PVC and does not require plasticizers.

For those in the audience with young children, you may be interested to know that Japanese researchers [Sugita et al. 2003] have reported average daily oral exposure of babies to phthalates from soft PVC toys of 21.4 µg/kg body weight/day.

**PAPER**

**Perfluorooctanoic acid**

Perfluorochemicals are widely used in the manufacturing and processing of a vast array of consumer goods, including electrical wiring, clothing, household and automotive products. Furthermore, relatively small quantities of perfluorochemicals are also used in the manufacture of food contact substances that represent potential sources of oral exposure to these chemicals. The most recognizable products to consumers are the uses of perfluorochemicals used as processing aid to make polytetrafluoroethylene (PTFE) commonly known as Teflon™ and used in non-stick coatings for cookware; they are also used to coat paper and make it oil and moisture resistant. In 2005 there were reports that fluoropolymers used in the manufacture of grease-resistant packaging for candy, pizza, microwave popcorn and hundreds of other foods are absorbed by fatty foods and then broken down by the body into the carcinogen perfluorooctanoic acid (PFOA).

In 2005 DuPont agreed to pay a record $10.25 million fine for failing to tell the EPA about its studies that found the chemical had contaminated human blood and should be considered ‘extremely toxic’. The company also agreed to pay another $6.25 million for research to evaluate the way PFOA degrades in the environment. The EPA had accused DuPont of failing to submit a 1981 study revealing that PFOA was passed from pregnant employees to their foetuses.

PFOA was labelled a ‘likely’ human carcinogen by the EPA in January 2006. In April 2006 a class action lawsuit was filed against DuPont due to PFOA contamination from its plant in Deepwater, New Jersey. In February 2007 DuPont announced that it had developed new technologies that will allow the company to eliminate PFOA from packaging by 2015. Meanwhile Boise Paper launched its first fluorochemical-free oil and grease resistant (OGR) paper in December 2006.

A new study published in April 2007 reporting that PFOA is showing up in newborn babies again raised concerns about the chemical's use as a protective coating on some food packaging. A study of about 300 umbilical cord blood samples by researchers at the Johns Hopkins Bloomberg School of Public Health found that newborn babies are
exposed to perfluorooctane sulfonate (PFOS) and PFOA while in the womb. These perfluorochemicals are biopersistent.

**Estrogenicity of Paper**

A very recent study [Lopez-Espinosa et al. 2007] reported on the estrogenicity of paper and cardboard used in take-way food packaging materials in four EU countries. Estrogenicity was demonstrated in 90% of samples. The authors concluded that paper and cardboard may contribute to the inadvertent exposure of consumers to endocrine-disrupting chemicals.

**RECYCLED MATERIALS**

**Plastics**

Recycled plastics may be contaminated by various household chemicals available to consumers. To prevent such contaminants reaching the food, a functional barrier is placed between the recycled plastic and the food. Functional barriers are used in multilayer structures and are deemed to prevent migration of undesirable substances from layers beyond the barriers into food [Feigenbaum et al. 2005].

The concept of a functional barrier has general relevance and may, in principle, be applied to any type of multi-layer structure. A functional barrier consists of one or more layers which either reduce the migration of authorised monomers and plastics’ additives below the SML or reduce the migration of non-authorised substances into foods or food simulants to a ‘not detectable’ level. These conditions may be achieved in several ways:

- through the use of an absolute barrier,
- by using a barrier layer which reduces migration to toxicologically insignificant levels, or
- via a barrier layer which provides sufficient migration lag time to limit the migration of a monomer or additive to toxicologically insignificant levels during the food contact period.

In contrast to glass or metals, which are absolute barriers above a minimum thickness, it is not possible to make general rules for plastics. The efficiency depends on the history of the polymer, of the material and of the finished article as well on their geometric properties, but mainly on thickness. Some general trends can however be drawn:

- Polyolefins and EVA are unlikely to behave as functional barriers, whatever the thickness of the layers.
- Other polymers such as PET, EVOH, PVC, PVDC, PAN may behave as functional barriers if the barrier layer is sufficiently thick. Virgin PET is generally regarded as the most effective plastic functional barrier.

**Paper**
In recycled paper it is well known that polychlorinated biphenyls (PCBs) can be contaminants from the historical use of carbonless copy paper (introduced in 1954), but following discontinuation of PCBs in the 1970s, their levels in recycled paper have declined so that there is no longer detectable migration into foods. More recently there has been a worldwide problem with the presence of diisopropynaphthalenes (DIPNs) in food packages [Boccacci et al. 1999]. DIPNs are widely used for ink-jet printers and as solvents in the preparation of specialty papers such as carbonless and thermal copy paper. As not all DIPNs may be removed by treatment of recycled fibres, some may be present in the finished board and thus under certain circumstances can migrate into food. For example, DIPNs have been detected in the UK in takeaway food packaging materials (paperboard rings around hamburgers) at levels ranging from 0.06 – 0.17 ppm in the food.

Trimethyldiphenylmethanes (TMDPMs), used as solvents in carbonless copy paper, have also been found in solid foods such as egg pasta and rice packed in paperboard containing recycled fibres. Maximum levels of TMDPM in the paperboard were 998 ppb and in egg pasta 34 ppb; DIPN was present at 72.9 ppb in the paperboard and 0.9 ppb in rice [Sturaro et al. 2006].

**PRINTING INKS**

Printing inks are incredibly complex materials and their detailed composition a closely-guarded trade secret. Over the past 20 years there has been a move away from solvent-based inks towards those that are cured by UV radiation or (less commonly) electron beams (EB). This move has been driven in part by the increasing legislative focus in developed countries on VOCs (volatile organic compounds) of which the solvents used in printing are a major source. Another reason that the use of UV-cured inks for printing cardboard and labels has become widespread is because the fast cure permits on-line cutting and folding, enabling rapid production of finished packaging. The unintentional transfer of components of printing inks from the outer printed surface onto the food contact surfaces is known as set-off or back migration. A number of food contamination incidents resulting from migration of photoinitiators into food have occurred and two examples will be given.

**Benzophenone**

Benzophenone has been widely used since the 1980s as a photoinitiator for inks and varnishes/lacquers that are cured with UV light. In addition to being a drying catalyst, benzophenone is an excellent wetting agent for pigments and acts as a reactive solvent, increasing the flow of inks. Such inks typically containing 5-10% photoinitiator. Since only a small portion of the initiator is used up during the curing process, benzophenone can remain in the printed material and migrate through the open structure of, for example, cartonboard into the packaged food. It may also be present if the cartonboard is made from recycled fibres recovered from printed material.

In the UK Johns et al. [2000] reported the migration of benzophenone from printed cartonboard at freezer temperature and during microwave heating. Benzophenone was
found to migrate into the packaged food, even from LDPE-coated board. After 1 week at -20°C, migration was readily apparent. Benzophenone was detected at levels which corresponded to a 1-2% transfer from the printed board, not enough to raise any health concerns.

In 2001 UHT milk packaged in HDPE bottles in Australia was recalled due to the presence of benzophenone (10 ppb) and benzaldehyde (25 ppb) which had migrated into the milk from the UV-cured ink used to print the labels, giving rise to a metallic taint and many consumer complaints. The levels of the benzophenone and benzaldehyde were well below those at which there might have been any health concerns and the strong odour and taste of the offending chemicals prevented their ingestion by consumers. Neither the dairy company nor the labelmakers were apparently aware of the potential for photoinitiators in ink to migrate and cause off-flavours in foods.

**Isopropylthioxanthone (ITX)**

ITX is another photoinitiator used in UV-cured offset printing inks and is always mixed with a co-photoinitiator (mainly EHDAB or 2-ethylhexyl-4-dimethylaminobenzoate). In 2002 a method was published by leading Swiss-owned global ink manufacturer SICPA [Papilloud & Baudraz 2002] to ascertain the level of UV ink ingredients (including the photoinitiator ITX) potentially available to migrate into food simulants. A 24 November 2004 patent application in the US by Sun Chemical (another major global ink supplier) noted: "In recent years, thioxanthone derivatives, particularly ITX and diethylthioxanthone, have been extensively used in UV curable printing ink applications. However, these are not entirely satisfactory because, following curing, unreacted thioxanthone derivatives of this type have a tendency to migrate from printing inks into, for example, packaged foodstuffs".

In September 2005 Nestlé undertook a recall in four European countries of UHT baby milk packaged in plastic foil laminate cartons following the discovery by Italian food safety authorities of the presence of the photoinitiator ITX and the related chemical EHDAB. The level of ITX ranged from 120-305 ppb for baby milk and from 74-445 ppb in milk for babies aged 12 months and over; ITX was found at 600 ppb in a single sample of flavoured milk tested. ITX was also found in chocolate and cocoa milk products sourced from Austria; in grapefruit juice and pineapple juice produced within Italy, and in milk and cocoa beverages from Germany.

Very recently, German researchers [Rothenbacher et al. 2007] detected ITX in 36 of 137 packages (26%) not limited to multilayer laminate cartons (e.g. it was found in sausage skins and plastic cups), and significant migration occurred in 75% of the packaging materials that tested positive. The levels of ITX ranged up to 357 ppb in orange juice. The authors concluded that industry should utilise other, less-migrating photoinitiators, and that the implementation of legislative standards for GMP with a positive list for printing inks and maximum migration limits, especially for substances with incomplete toxicological assessment, is essential.
ITX is not prohibited for use in food packaging by the EU; it is also not listed on the WHO’s prohibited list. The European Food Safety Authority (EFSA) said scientific evidence indicated that the presence of the chemical in packaged foods does not pose a health risk. A draft EU law proposed after the crisis is currently under debate; the text is aimed at clarifying the principles of good manufacturing practice in respect of materials and articles intended to come into contact with foods and introducing specific rules for printing inks.

Tetra Pak (manufacturer of the Nestlé cartons) has stated publicly that it is no longer using ITX in its printing inks. ITX differs from benzophenone in that there is no obvious off-taste or odour to alert consumers to its presence in the food. If the largest food company (Nestlé) and the second-largest packaging company (Tetra Pak) in the world with all their technical resources and quality management systems operating within the EU with its plethora of laws and regulations were unaware of the potential of ITX to migrate via set-off onto the food contact surface and subsequently into the food, then what hope is there for smaller, less well resourced companies to avoid similar mishaps?

**TRACEABILITY**

One of the consequences of globalisation is that it has become more difficult to trace the origin of our foods and the packaging which surrounds them. Regulatory authorities simply cannot analyse every package on the market for the thousands of possible contaminants that may be present in the packaging material, the adhesives, the ink or the food itself. As the ITX incident showed, even the world’s largest food company and second largest packaging company are not able to guarantee that their products and packages are free from undesirable contaminants. So what hope for the smaller players and the importers who are largely unaware of possible pitfalls? And with the increasing quantity of food packaging materials containing recycled content, are there adequate safeguards to ensure that no contaminants are present?

Traceability has become an integral requirement of modern quality management systems. In the EU, Article 17 of Regulation 1935/2004/EC requires food contact materials or articles to be unequivocally identified when they are shipped to the next operator in the value chain [Dainelli 2007]. For materials or articles sourced from outside the EU, traceability extends back to the importer responsible for putting them on the EU market for the intended food contact application. Just how successfully the importer could trace back the origin of the material is unknown.

**CONCLUSIONS**

Why do these contamination issues continue to bedevil the food industry? Is the food industry less than rigorous in evaluating food contact materials? Is legislation or enforcement of it too lax? Is the complexity of the task beyond the capabilities of even well-funded regulatory authorities? And more importantly, should we as consumers be concerned about the health implications of these contaminants in our food? This presentation has attempted to answer these and other questions related to the safety and
health implications of food contact materials.

I don’t believe that there is any justification for consumers to panic. However, it is imperative that professionals in the food industry lobby governments to increase funding for food surveillance work. As well, there is a need for continuing education of food industry professionals so that they are aware of possible problems before they occur. Although I have no association with it, I strongly recommend that all food companies subscribe to the journal *Food Additives & Contaminants*; every issue has at least one article about possible contaminants from packaging materials, as well as many other highly relevant articles. A guide to internet resources on food safety is also useful [Gilardi & Fubini 2005].

There is an old saying much loved by the defence industry that ‘*the price of freedom is eternal vigilance*’. This is just as true to ensure a food supply free from undesirable contaminants as it is to preserve our democracies. We need to act now before a major contamination scare undermines the public’s confidence in the food supply. But it is impossible to foresee every potential contamination issue because of what Donald Rumsfeld described as the Unknown Unknowns.

“The question of al Qaeda’s weapons of mass destruction capability was what Rumsfeld often called a ‘known unknown’ – something they knew they didn’t know, something both possible and important but on which they had no definitive intelligence. It was chilling in itself. But it was in some ways less of a concern that the ‘unknown unknowns’, the things that the US didn’t know it didn’t know, the potential ugly surprises”.

Bush at War by Bob Woodward (2004)

What ‘unknown unknowns’ or ugly surprises await food regulatory authorities around the world in relation to food packaging and in particular contaminants that may enter foods from food contact materials? By their very nature, it is impossible to answer this question. However, examination of the crises over the last few years that have generated global publicity as a consequence of the discovery of, for example, ITX, ESBO and SEM in baby foods reveals that no existing regulatory system is perfect, and that there is room for improvement in all existing systems. However, as the specific examples illustrated, there is nearly always prior knowledge by some persons of the likely migration of food contaminants from food contact materials into foods; flushing this information out and making industry aware before a crisis arises is the challenge for both food manufacturers and regulatory authorities.
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