

# final report

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# Feasibility of using linerless cartons for the storage and transport of meat and meat products

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# **Executive summary**

Poly-entrapment, as a result of the use of conventional carton liners, is becoming an increasing concern both from a public health point of view and because of the commercial costs associated with its control and removal. This project assessed the chemical, physical and microbiological risks associated with the use of linerless cartons for the storage and transport of meat and meat products. In addition, commercial trials were undertaken to determine the integrity of linerless cartons in trade.

An initial chemical risk assessment was undertaken to estimate the impact of the use of linerless cartons on the export of frozen bulk-packed meat. The assessment was based on a study of extractables from linerless cartons undertaken at Rutgers University in the US. US, EU and domestic requirements under the Australian standard were considered when evaluating risk. Migration of chemical compounds of concern were either below the US threshold of regulation limits or EFSA thresholds of toxicological concern or were below published total dietary intake values where available. Based on the findings of the assessment it was concluded that exposure to chemicals through migration from the linerless carton is minimal and below regulatory limits. It is recommended that migration studies using current plastic liners are undertaken for comparison purposes.

A rapid method utilising adhesive tape was developed for visualisation of physical contaminants on linerless carton contact surfaces. It was found that the level of physical contamination on linerless cartons was similar to that on conventional plastic liners and should not pose a risk to consumers. Contamination by fibreboard "off-cuts" should be monitored and interventions put in place by the carton manufacturer if this become an issue in the future.

The microbial load on the contact surface of linerless cartons was not significantly different from that on conventional liners, suggesting no increased microbial risk from the use of linerless cartons.

Work instructions and SOPs were examined to determine their relevance to processing using linerless cartons. The department outlines specific requirements for the hygienic use of cartons, including linerless cartons and these need to be addressed. In general, storage and handling WI's and SOP's are adequate for the control of contamination of linerless cartons, although some modifications are required, particularly in relation to storage and lidding practices.

Domestic and international trials demonstrated that the integrity of the linerless cartons could be maintained from packing through to final processing. Carton damage during transportation seemed to be consistent with that observed using traditional cartons, although more data is needed to see if product condemnations are similar between the two carton types. A common issue with linerless cartons was the inability of operators to initially remove product without contaminating the meat. With proper training these issues were resolved. Tempering resulted in some degradation of cartons due to moisture migration to the outer cardboard layer; while not raised as an issue, this needs further investigation as does possible issues around freezer burn. In general customers were happy with the results of the trials.

Use of linerless cartons appears to be a viable option for the storage and transport of meat. Future work should quantify the impact of damaged cartons, further investigate the effect of tempering on carton integrity and compare the incidence of freezer burn with conventional packaging.

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# 1 Background

Use of liners in cartons is necessary to minimise microbial and physical contamination of meat from the cartons and environment, and to ensure that weep from product does not damage cartons resulting in exposure of product to the environment. A major disadvantage of conventional poly-liners is entrapment of the liner during freezing and the subsequent difficulty in ensuring product destined for further processing is not contaminated with liner material. Entrapment poses both a human health risk and significant commercial cost to industry.

As with all proposed changes to processing there is a need to produce data to support the continued wholesomeness of product. The data in this report will support the safety of linerless cartons and assist the Department of Agriculture and Water Resources (the department) in equivalence negotiations with importing country authorities.

This report contains an assessment of the chemical, physical and microbiological risks associated with the use of linerless cartons for the storage and transport of meat and meat products, as well as the result of domestic and international commercial trials.

# 2 Project objectives

# 2.1 Objectives

- Undertake an assessment of the risks associated with possible chemical migration from the linerless carton to the meat;
- Undertake an assessment of the physical and microbiological risks associated with the use of linerless cartons;
- Develop work instructions for the handling and storage of linerless cartons; and
- Assess the integrity of linerless cartons in trade

# 2.2 Outcomes

- Documented procedures for the handling, packing and storing of linerless cartons
- Scientific justification for the use of linerless cartons that the department can utilise in equivalence discussions with key export markets

# 3 Methodology

# 3.1 Chemical risk assessment

A migration study was undertaken by Rutgers University (Rutgers 2016) using the Visy Blue Linerless Carton to determine compliance with the requirements of United States (US) CFR 21 176.170. The food simulant used was 95% ethanol as recommended by the United States Department of Agriculture (USDA) Food and Drugs Administration (FDA) (FDA 2007) for specific polymers. It should be noted however that the use of 95% ethanol as a simulant may overestimate the migration figures obtained for some food-contact polymers. The results of the migration study were compared to the

requirements outlined in Australian Standard 2070 – Plastics Materials for Food Contact Use (1999) and either FDA CFR Title 21 Parts 170-199 or relevant European Commission directives. The risk assessment only considered the data provided by Visy that was relevant to the Australian Standard requirements and the FDA regulations i.e. extractable data and heptane results.

# 3.2 Physical risk assessment

A relatively simple semi-quantitative technique as described in ISO 8502-3 was used for assessing physical contaminants on linerless cartons. Commercially available tape (Scotch Every Day Tape) measuring 19 mm wide was used to assess physical contamination on the carton surface. Briefly, approximately 20 cm of tape was removed from the roll and discarded to ensure that tape used for measuring physical contamination was as clean as possible. Approximately 20 cm of tape was then removed from the dispenser and placed on the carton surface in the middle of face 5 (bottom contact surface). The tape was adhered to the surface by running a finger along the tape ~10 times applying light pressure while holding one end of the tape to facilitate removal. The tape was then carefully removed from the surface and transferred to a clean piece of A4 paper. The number of contaminating particles were quantified and compared to contamination recovered from contamination from fibreboard offcuts.

# 3.3 Microbiological risk assessment

Samples were collected from 100 cm<sup>2</sup> of surface using a WhirlPac<sup>™</sup> sponge. Briefly, dehydrated sponges were rehydrated with 5-10 ml of Butterfields diluent taken from a 25ml container that was labelled and retained so that the remaining diluent could be added after sample collection. Hydrated sponges were carefully removed from their plastic bag and placed onto the surface to be sampled. The sponge was handled either by inverting the sample bag and using this to hold the sponge during sampling or using a sterile disposable clove. Approximately 100 cm<sup>2</sup> of surface was sampled by rubbing the sponge 5 times in a vertical and 5 times in the horizontal direction. Sponges were returned to the bag and the remaining diluent added to give a total volume, in the bag, of 25 ml. Sponges were packed in a container and transported to the testing laboratory under refrigeration.

Samples were analysed at a NATA accredited laboratory (department approved) for aerobic plate count (APC) at 30 °C for 72h, following the requirements of AS 5013.1. The colony forming units (CFU) per cm<sup>2</sup> were estimated and reported. Where samples were analysed using Petrifilm the procedure outlined in AOAC 990.12 was followed.

Blue plastic bags (n=30) currently used to line cartons prior to packing were sampled by collecting 30 bags from the production floor. Bags were then sampled using the procedure outlined above. Linerless cartons were sampled over two days. On the first day cartons (n=10) were sampled as outlined above for the plastic liners i.e. not on the production floor. These ten samples were also analysed using APC Petrifilm to evaluate this method for ongoing monitoring of contact surfaces. On the second day 20 linerless cartons were sampled on the production floor immediately prior to packing. Samples were sent to the testing laboratory and analysed within 24h of collection.

Analysis of results was carried out using R 3.3.2 (Copyright 2016).

# 3.4 Development of work instructions

A review of an export processing plant's current work instructions (WI) and standard operating procedures (SOPs) relating to carton receival, handling and storage was undertaken to determine if

there were any issues in relation to the introduction of linerless cartons into production. A walk through of the operation was carried out to identify areas were specific intervention for linerless cartons may need to be implemented. In addition, an audit of the Visy Industries Holdings Pty Ltd manufacturing facility at Staplyton QLD was carried out to determine if there were any contamination issues that needed to be addressed at the Visy plant.

# 3.5 Carton Integrity

Fabricated linerless cartons were supplied by Visy as a base erector had yet to be installed at the processor. Cartons were handled under the modified WIs and SOPs developed as part of this project. Linerless cartons were integrated into normal product and packed as per current protocols. Packed cartons were then lidded and frozen normally. After freezing cartons were palletised and wrapped before being dispatched to domestic and international customers. Feedback was sort on the integrity of the cartons on arrival at the customers' facility and on the ease of opening. Processor company staff were able to attend both domestic trials and one of the international trials.

# 4 Results

# 4.1 Assessment of the chemical risk associated with the use of linerless cartons

#### 4.1.1 Introduction

The scope of this assessment was limited to chemical hazards that might impact on the export of frozen bulk-packed meat to the United States of America (US). Consideration was also given to domestic requirements by the Department of Agriculture and Water Resources (the Department) and Food Standards Australia and New Zealand (FSANZ), under the Australian Standard.

The Department has published a guideline for the use of liner-less cartons at export registered establishments. This guideline specifies that plastics in contact with meat must comply with the requirements of Australian Standard 2070 – Plastics Materials for Food Contact Use (1999). AS 2070 Clause 4.1.1 *New Plastics Materials* specifies that new plastics must comply with either United States Department of Agriculture (USDA) Food and Drugs Administration (FDA) Code of Federal Regulations (CFR) Title 21 Parts 170-199 or relevant European Commission directives. Further to this, he standard requires colourants to comply with Council of Europe Resolution AP (89) 'Resolution on the use of colourants in plastics materials coming into contact with food'.

Meat derived from cattle in the US, both domestically produced and imported, is regulated by the USDA Food Safety Inspection Service (FSIS). FSIS however do not actually specify requirements for packaging materials contacting product, instead the FSIS require all such products to comply with FDA requirements. FDA regulates food packaging that contacts with food under Code of Federal Regulations (CFR) Title 21 - 174 – *Indirect Food Additives* and in the case of carton material CFR 21 Part 176 – *Substances for Use Only as Components of Paper and Paperboard* (2015).

The current assessment draws heavily from the FSANZ risk profile produced as part of Proposal P1034 – *Chemical Migration from Packaging into Food* (FSANZ 2016).

#### 4.1.2 Hazard identification

Synthetic polymers typically have a high molecular weight and are therefore not biologically active. However, the presence of lower molecular weight additives as well as unreacted monomers means that there is the potential for human exposure as a result of migration of these chemicals into food. Migration chemicals include monomers, catalysts, solvents and additives such as antioxidants, antistatics, antifogging agents, slip additives, heat and UV stabilisers, dyes and pigments (Pocas and Hogg 2007). There are potentially thousands of chemicals and their derivatives or break down products that may migrate from packaging materials to foods, however, recently the focus has been on a few key compounds.

#### 4.1.2.1 Bisphenol A (BPA)

BPA (2, 2'-bis (4-hydroxyphenyl) propane) is used in the production of polycarbonates (hard plastic containers, such as baby bottles) and in coatings used as liners (i.e. in cans). BPA has been found in low levels in foods and has been shown to adversely affect the liver and kidneys in animal studies as well as having developmental effects on the young. There is particular concern over the use of BPA in materials used for the packaging of infant foods. However, both EFSA and FDA have concluded that current exposure levels do not result in any adverse human health outcomes. Nevertheless some food manufacturers have banned the use of BPA in their food containers.

#### 4.1.2.2 Plasticisers

Phthalates (esters of phthalic acid) are of concern as they typically have high rates of migration to foods and have been shown to cause adverse health effects in animals. Of the phthalates, diethylhexyl phthalate (DEHP) is of most concern and is the subject of several regulations in the US. The EU has set a 'specific migration limit' (SML) for DEHP of 1.5 mg/kg food. Di-isononyl phthalate (DINP) is sometimes used as a substitute for DEHP and other lower molecular weight phthalates (FSANZ 2016). DINP is generally considered to be less hazardous than DEHP, although it has still been shown to cause adverse effects in rats at relatively high doses. Other phthalates have been shown to migrate to foods but generally at lower levels and are found less often that DEHP and DINP. These other phthalates are not considered to present any public health risk.

#### 4.1.2.3 Printing inks

Printing inks were identified as chemicals of concern in the FSANZ risk profile (FSANZ 2016), this class of chemicals should not be of concern in cartons manufactured from non-recycled components, but they may be present in recycled fibres and migrate to foods through the plastic lining. Of interest are benzophenone and 4-methylbenzophenone which are typically used as initiators for printing inks cured by UV radiation. Some regulators have classified benzophenone as carcinogenic, although the European Food Safety Authority (EFSA 2009) concluded that benzophenone has no genotoxic potential but can cause adverse effects to the liver.

#### 4.1.2.4 Antioxidants

Antioxidants are used in packaging materials to delay the degradation of plastics.

#### 4.1.2.5 Perfluorinated Chemicals

Perfluorinated chemicals (PFCs) are used in the manufacture of grease-proof coatings for paper wrappers and paperboard containers. Some of these compounds have been shown to

bioaccumulate and produce adverse health effects in animal studies, including reproductive and developmental toxicity.

#### 4.1.2.6 Mineral Oil Hydrocarbons

Consumers are exposed to a range of mineral oil hydrocarbons (MOH) in foods either from the food itself or because of migration from packaging to the food. Classification of MOH is analytically difficult and these compounds are typically divided into mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH). While full exposure pathways for MOH are not clearly defined, food packaging and additives, processing aids and lubricants play a role. Although broadly toxicological data is inconclusive, certain MOSH have been shown to produce microgranulomas in the liver of rats while some MOAH can act as cancer promotors (EFSA 2012).

#### 4.1.3 Hazard characterization

As stated previously the number of chemicals found in packaging, capable of migrating to foods, is large. While toxicological data are available for some of these compounds for others data is not well defined or lacking. Because of the enormity of undertaking toxicological studies on all compounds that might migrate to foods, regulators have taken a risk-based approach based on the level of exposure of consumers to these chemicals (FSANZ 2016). If migration levels are shown to be sufficiently low, toxicological data may be deemed unnecessarily in order to conduct a risk assessment for regulatory purposes.

The risk posed by some of the chemicals found to migrate to foods have been extensively studied and acceptable exposure levels have been defined. Most notable of these are BPA and diethylhexyl phthalate (DEHP).

EFSA have concluded that current dietary exposure to BPA does not result in any adverse health effects. Nevertheless, EFSA have recommended reducing the TDI for BPA to  $4 \mu g/kg bw^*/day$  based on currently estimate exposure levels and have removed approval for use of BPA in some products i.e. infant formula bottles. BPA appears on the Californian Office of Environmental Health's list of chemicals of concern (COEH 2016) but a no significant risk level (NSRL) has yet to be set.

Diethylhexyl phthalate (DEHP) and other phthalates are used as plasticisers in some types of packaging films, although many companies are looking at phasing out the use of phthalates. DEHP has been shown to have adverse reproductive and developmental effects in animal studies. A TDI of 50  $\mu$ g/kg bw/day has been proposed by EFSA; similarly, a NSRL of 310  $\mu$ g/day (~52  $\mu$ g/kg bw/day) has been proposed by the COEH (2016). The FDA has recommended a Tolerable Intake (TI) for DEHP of 40 $\mu$ g/kg bw/day. Other phthalates such as Di-isononyl phthalate (DINP) are less toxic than DEHP and are sometimes used as a substitute for DEHP. EFSA has established a TDI of 150  $\mu$ g/kg bw/day for DINP (FSANZ, 2016). The TDI for other phthalates such di-butyl phthalate (DBP) are also regulated (10  $\mu$ g/kg bw/day).

Benzophenone appears on the COEH (2016) Prop 65 list of chemicals of concern, although a NSRL has not been published. EFSA has recommended a maximum TDI for benzophenone of 30  $\mu$ g/kg bw/day.

 $<sup>^{*}</sup>$  Kilograms body weight (kg bw) based on an average weight of 60 kg

Acceptable Daily Intake (ADI) values have been recommended by the WHO for various classes of MOH. Generally, the lower the viscosity of the hydrocarbon the lower the ADI. In the absence of toxicological data on low viscosity MOH's a conservative ADI of 0.01 mg/kg bw/day has been temporarily established (EFSA 2012). This figure is under review as EFSA (2012) estimated exposure levels 30 times this limit, although they point out that not all the MOHs measured were low viscosity MOHs.

There are many other chemicals that could cause adverse health effect in humans at high concentrations. However, generally these chemicals are present in foods below levels of concern. In order to estimate the risk from these other chemicals regulators sometimes consider toxicity data from structurally related chemicals to support their safety evaluation (FSANZ, 2016). Alternatively, for substances with limited or no toxicity data, the threshold of toxicological concern (TTC) approach can be used for safety assessment. This approach sets a daily exposure limit for different classes of chemicals. EFSA/WHO (2016) recommended a TTC for suspected genotoxic substances of 0.15  $\mu$ g/person/day (0.0025  $\mu$ g/kg bw/day), with less restrictive values recommended for other chemical classes i.e. 90  $\mu$ g/person/day (1.5  $\mu$ g/kg bw/day) or higher. A similar approach is taken by the FDA for non-carcinogenic chemicals through application of a Threshold of Regulation (TOR)<sup>+</sup> i.e. 1.5  $\mu$ g/person/day.

#### 4.1.4 Exposure assessment

Chemical migration generally is restricted to smaller molecular weight molecules; with the rate of migration dependent on both intrinsic (inherent properties of the food and film) and extrinsic (environmental conditions) factors. Generally, migration is more likely into fatty foods and will be faster at higher temperatures (Bhunia et al 2013).

The following exposure assessment relates only to the use of linerless carton technology as a packaging material for beef. The linerless carton consists of board grade 560MLK-B and paper makeup K205HP (M150) MLK205 and contains a release coating on the food contact surface. The coated fibre board (minus the blue dye) is currently approved as a packaging material in the poultry industry. Visy attests that the release coating in the blue linerless cartons is certified for direct food contact applications as per the requirements in CFR 21 176.170<sup>‡</sup>.

A summary of the results of the migration study undertaken by Rutgers University (Rutgers 2016) is provided below.

#### 4.1.4.1 Migration report summary

The total extractives from the food contact surface was estimated using heptane following the protocols in CFR 21 176,170 (food type III; conditions of use F and G i.e. 21°C for 30 minutes). Total extractives were estimated at 0.3 mg/in<sup>2</sup> (without correction factor<sup>§</sup>). This is less than the regulatory limit of <0.5 mg/in<sup>2</sup> specified in the CFR.

<sup>&</sup>lt;sup>+</sup> USDA FDA CFR 21 170.39 Threshold of regulation for substances used in food-contact articles

<sup>&</sup>lt;sup>‡</sup> USDA FDA CFR 21 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

<sup>&</sup>lt;sup>§</sup> Because of the known variance in the exaggerative effect of heptane relative to food, migration values should not be divided by a factor of five as specified in the CFR (FDA 2007)

Migration studies were undertaken at 20°C for 10 days using 95% ethanol as recommended in the FDA guidelines (FDA 2007) for the worst-case scenario of applications under refrigerated conditions . Extractable chemicals were quantified in the 95% ethanol (food-side) using Gas Chromatography/Mass Spectrometry (GC-MS) and the concentration reported as PPB (parts per billion or  $\mu$ g/L) in the food simulant (95% ethanol). The total amount of extractables migrating from the coating applied to a typical carton (522x350x158 mm) was calculated by multiplying the ng/cm<sup>2</sup> values quoted in the report by the total surface area. This was then divided by the total weight of meat (27.2kg). These values were then used to determine a correction factor for PPB values of 0.36. To estimate dietary exposure the 0.36 correction factor was applied to the concentration of hazard in the simulant to obtain an estimate of the concentration of substance that might be found in meat packaged in linerless cartons. A further factor of 0.1 was applied to allow for the estimated daily consumption of meat i.e. 100g/person/day<sup>#</sup>. The extraction experiment was performed in triplicate. Average results are discussed except were specifically stated otherwise.

Most of the extractables report in the migration study would result in exposure levels below the FDA TOR of 1.5  $\mu$ g/person/day; remembering that extraction conditions were worst-case. All of the individual compounds listed in the Rutgers report were found at levels below the TTC recommended by the EFSA/WHO for non-carcinogens i.e. 90  $\mu$ g/person/day.

#### 4.1.4.2 Exposure to chemicals of potential concern

The average BPA level in the simulant was 26.5  $\mu$ g/L resulting in an estimated exposure of 0.016  $\mu$ g/kg bw/day<sup>\*\*</sup>. This figure is well below the EFSA recommended total dietary intake (TDI) to 4 ug/kg bw/day and US estimated TDI of 2.4 ug/kg bw/day (FDA 2008; note that this draft assessment on the risk of BPA has been withdrawn).

Total Phthalates in the simulant were in the order of 180  $\mu$ g/L; well below the levels established for phthalates in the EU (1,500  $\mu$ g/kg for DEHP and 300  $\mu$ g/kg for DBP). DEHP (including dioctylphthalate, DOP) was present in the simulant at the highest concentration i.e. 109  $\mu$ g/L (40  $\mu$ g/kg or 0.07  $\mu$ g/kg bw/day) while the level of DBP was 71  $\mu$ g/L (26  $\mu$ g/kg or 0.04  $\mu$ g/kg bw/day). The COEH has set a maximum dose for DBP of 8.7  $\mu$ g/day, given a meat consumption of 100g this would equate to a daily exposure limit of 87  $\mu$ g/kg of meat. The COEH maximum dose for DEHP is 310  $\mu$ g/day.

Benzophenone was found in the simulant at a level of 24  $\mu$ g/L (8.8  $\mu$ g/kg or 0.15  $\mu$ g/kg bw/day). This is below the EFSA derived TDI of 30  $\mu$ g/kg bw/day.

In the Rutgers study, MOSH and MOAH were detected in the simulant at levels of 14.37 mg/L and 0.101 mg/L, respectively. EFSA estimates exposure to MOSH to be up to 0.3 mg/kg bw/day (EFSA 2012). To estimate exposure from the meat associated with the linerless cartons, the simulant concentration was multiplied by the factor described previously (0.36) to obtain an estimate of the  $\mu$ g/kg concentration. The concentration in meat was then divided by 10 to give the concentration consumed per day (i.e. 100g of meat consumed per person per day) and further divided by 65 kg (average weight of an individual) to obtain an estimated daily exposure of 0.008 mg/kg bw/day. This

For refrigerated or frozen food applications, the recommended test temperature is 20°C

<sup>&</sup>lt;sup>#</sup> Based on US consumption figures reported by the USDA Economic Research Service in 2015

<sup>\*\*</sup> Assuming a daily consumption of 100g by a 60kg person

estimated exposure is less than the highly conservative ADI (0.01 mg/kg bw/day) recommended by the WHO and as pointed out by EFSA (2012) the exposure figure is a mixture of all MOH classes not just those with low viscosity. Therefore, the levels of MHOs migrating to meat from the linerless carton do not pose a human health risk.

Based on the findings of the Rutgers migration study it is concluded that exposure to chemicals through migration from the carton liner detailed in this report is minimal and below regulatory limits.

# 4.2 Assessment of physical contamination associated with the use of linerless cartons

#### 4.2.1 Introduction

The scope of this assessment was limited to physical hazards associated with linerless cartons immediately prior to use. Consideration is only given to those physical hazards associated with the cartons i.e. does not include physical hazards associated with product such as bone, lead shot etc. Physical contamination on the contact surfaces of the carton can transfer to the meat during packing and storage. Also, glue used in preparing and sealing the carton and the liner itself (through delamination) can contaminate product.

#### 4.2.2 Hazard identification

Physical contaminates associated with contact surfaces of cartons are limited to those contaminants that transfer to the blanks during manufacture, transportation and carton assembly. Carton material either in the form of dust or small pieces of fibre board will be the most likely contaminant although environmental dust may contaminate blanks during storage if they are not appropriately covered. Contamination with carton material is exacerbated by the necessity of storing blanks with coated sides in contact with fibre board of the adjacent blank. Contamination is primarily controlled during the manufacturing process at Visy. Contamination with glue is an operational hazard and will be controlled through adjustment of the lidding machine during operation. Glue monitoring programs should ensure that this hazard is adequately controlled. Similarly, delamination of the carton liner is a physical defect of the carton and is controlled by the manufacturing process. Monitoring of delamination with feedback to the manufacturer will control any likelihood of physical contamination of product.

#### 4.2.3 Hazard characterization

Physical contamination of the type likely to occur because of the use of linerless cartons does not pose a significant health risk to consumers. No references were found for adverse health effects associated with consumption of fibre board particles. It is therefore concluded that the human health risk associated with exposure to fibreboard off-cuts and dust particles is negligible; although given consumer aversion to any contamination of food the commercial consequences may be significant.

#### 4.2.4 Exposure assessment

Physical hazards associated with cartons are only a concern on contact surface where the carton liner is in contact with the meat. Preliminary trials using an adhesive tape technique were carried out on linerless carton blanks that had been stored at the processor for several weeks. There was no sign of delamination of the carton liner as a result of removing the tape. No fibreboard off-cuts were present on any of the cartons examined. The tape was placed on a piece of white A4 printing paper so that the surface that contacted the sample was between two lines, 13.16 cm apart, thus delineating an area of 25 cm<sup>2</sup> (Fig. 1).

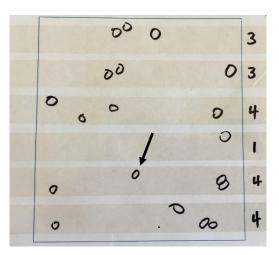


Fig. 1 Pressure sensitive tape technique for the determination of surface cleanliness. Tape samples from six (6) carton blanks appear as horizontal shaded zones. Circled areas are visible contaminating particles with the total number of particles per 25 cm<sup>2</sup> shown on the right. Arrow shows particle enlarged in Fig. 2.

Contamination was enumerated using the naked eye. Particles appearing on the edge of the tape were excluded from the count on the assumption that they were likely the result of contamination of the tape prior to use. Particles were generally very small and dark in colour (Fig. 2).

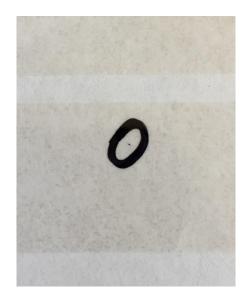


Fig. 2 Enlarged image of a typical contaminating particle visualised on tape samples from linerless carton blanks.

The average number of contaminates found on carton blanks (n=10), stored for several weeks at the processing plant, was 3.3 per 25 cm<sup>2</sup> (maximum = 6 per 25 cm<sup>2</sup>)

To obtain a baseline for reference, surface contaminants were enumerated on current blue plastic liners. Liners (n=25) were removed from the boning room and sampled using the above procedure. The average contamination level found on blue plastic liners was 1 per 25 cm<sup>2</sup> (maximum = 5 per 25 cm<sup>2</sup>).

The level of contamination adhering to tape samples was generally low and certainly less than the highest quality level provided in ISO 8502-3. However, as this standard does not relate to food contact surfaces it is not possible to draw any conclusions based on these quality standards. Based on size references provided in ISO 8502-3 most contaminants measured on carton and liner surfaces were between 50  $\mu$ m and 100  $\mu$ m in diameter i.e. just visible with normal or corrected vision.

A similar assessment was carried out on 20 linerless cartons used in the first commercial shipping trial. Product was packaged on the 02/01/2017 and surface samples were collected in the boning room immediately prior to packing. Cartons had been freshly supplied to the processor by Visy for the purpose of this trial, however cartons had still been stored for several months prior to sampling. The average number of contaminating particles visible on the tape was 2.95 per 25 cm<sup>2</sup> (maximum = 7 per 25 cm<sup>2</sup>). These results are consistent with those reported above for the initial sampling of linerless cartons and similar to those obtained from plastic liner samples.

# 4.3 Microbiological contamination associated with linerless cartons

#### 4.3.1 Introduction

Bacteria can contaminate fibreboard during manufacture. This is especially true for recycled fibreboard where large numbers of microorganisms can potentially be present, depending on the controls implemented during its manufacture (Hladíková et al 2004). While this contamination is important it is found throughout the fibreboard and may not necessarily transfer to the product during storage i.e. migrate through the plastic liner. Cartons used in the trial outlined below were manufactured from virgin fibreboard and it is not clear what effect this may have on the level of bacteria present in the board. Bacteria can also contaminate carton surfaces after manufacture, particularly during storage if steps are not taken to protect blanks from airborne contaminants, such as dust. To determine the significance of microbial contamination of surfaces, samples were collected from traditional liners (to establish a baseline level) and from linerless carton contact surfaces.

#### 4.3.2 Results

Microbial counts on contact surfaces from the current system and from linerless cartons are compared in Fig. 3. The data in Fig. 3 was censored by assigning a value of  $0.1 \text{ CFU/cm}^2$  to samples that were below the limit of detection of the method i.e. <  $0.25 \text{ CFU/cm}^2$ .

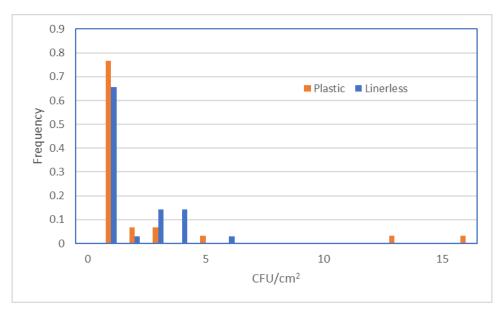


Fig. 3 Distribution of APC on plastic liners and linerless cartons. Data censored by assigning a value of 0.1 CFU/cm<sup>2</sup> to samples with APC below the limit of detection

Log transformed data were analysed for any significant difference using the AOV function in R. There was no significant different between the aerobic plat count obtained from linerless cartons and from conventional liners (p=0.867). Counts obtained on Petrifilm were comparable to counts obtained using the standard method.

### 4.4 Development of work instructions for handling linerless cartons

#### 4.4.1 Introduction

The utilisation of linerless carton technology by the processor requires the company to review its current work instructions (WIs) and standard operating procedures (SOPs) to determine their currency. As linerless cartons are essentially a meat contact surface additional safeguards are required for their transport and handling prior to carton closure. The following details what might be considered best practice in the handling of linerless cartons. Interventions identified in this report cannot be validated until the technology has been fully implemented. An audit of the Visy plant was also undertaken to identify possible sources of contamination of blanks and lids. The results of this audit are provided in Appendix 1.

#### 4.4.2 Best practice for the handling of linerless cartons

Practices relating to the handling of linerless cartons have been summarised by the department<sup>++</sup>. The following general criteria apply for the use of cartons at export establishments and these criteria equally apply to linerless cartons (DAWR 2014).

A carton shall not be deemed acceptable for packaging prescribed goods unless it complies with the following criteria in that the carton:

i) Protects the product and the product wrap from external contamination

<sup>&</sup>lt;sup>++</sup> <u>http://www.agriculture.gov.au/Style%20Library/Images/DAFF/\_\_\_data/assets/word\_doc/0004/2366590/linerless-carton-approval.doc</u>

- ii) Is not detrimental to the temperature status of chilled or frozen prescribed goods
- iii) Permits detection of penetrating foreign objects once carton has been closed and/or sealed
- iv) Complies with the Australian standard (AS 3724)
- v) Is inscribed with the Australian standard (AS 3724 compliance logo)

While the department has approved the use of linerless cartons in export meat establishments, the following requirements relating to their physical make-up should be considered.

- i) The linerless cartons are to have a plastic laminated film attached to the internal surface of the carton during manufacturing.
- ii) The plastic is to extend over the entire inner surface.
- iii) The base usually has flaps folded over the outside so that the corrugated cut edge of the carton base is not exposed to any moisture or product contact.
- iv) The carton must carry a statement that it complies with Australian Standard AS 3724 or that the carton has been approved by the department for export and identified with an approval number.
- v) The carton is to be leak proof when sitting on its base with no exposed cut edge on the inner surface which could contaminate or lead to adhesion to the contents.
- vi) The product contact surface must comply with AS 2070 or be approved by the department as a food grade plastic.

The following practices should be considered in relation to the transport, storage and handling of linerless cartons.

#### Transport

- i) The palletised cartons are to be wrapped with plastic or cardboard on all sides, top and bottom so that the cartons are protected from dust and other contaminants.
- ii) Linerless cartons are to be segregated from non-linerless cartons.

#### Storage

- i) On delivery, the palletised cartons must be put into an approved carton storage facility and not held in the open.
- ii) Storage areas for linerless cartons must be clearly distinguished from areas for other carton types.
  - If linerless carton blanks are imprinted with a statement indicating that plastic liners are not required to be used with the assembled carton then segregation is not required.
- iii) When the pallet is opened, the cartons must be protected to the same level of control provided to plastic liners e.g. that cartons are covered, not held unprotected on racks and good handling practices employed.
- iv) Cartons remaining on the pallet must be effectively protected from contamination i.e. shrouded.
- v) The cartons must be covered/protected during delivery to the production room(s).
- vi) Where plastic coating is exposed e.g. lids, the cartons are to be layered so that there is plastic to plastic contact between cartons, ensuring plastic to fibreboard does not occur at anytime.

#### Handling

i) Only enough cartons for the production run should be brought into the production room so that the need to return unused cartons to the carton store is minimised

- Cartons must be checked before packing of product for incidental contamination by carton fibres and if present the contamination must be removed in a way that doesn't cause the direct or indirect contamination of prescribed goods
- iii) The cartons must be protected from water splash
- iv) Care is to be taken when filling the cartons, so the carton does not bulge in the centre which would increase the possibility of carton damage and breakage
- v) The establishment must have procedures under its approved arrangement for the handling of cartons (used or unused) and these must be complied with.

Damaged cartons must be identified prior to load-out where possible. The consideration should be given to the following;

- i) Damaged cartons where the meat is liable to be exposed is to be rejected from loading
- ii) Removal of any contaminated meat is to be done prior to re-cartoning of product from damaged cartons
- iii) Establishments must be careful that overseas rejections are not increased because of exposed or contaminated meat in liner-less cartons.
  - Where carton damage has occurred, but the liner remains intact importing country authorities may permit entry of the product. However, this situation is unlikely to apply to damaged liner-less cartons.

#### 4.4.3 Review of current practices

The processor's WIs and SOPs were reviewed for their currency in relation to the transport and handling of linerless cartons, blanks and lids. It was assumed that references to boxes and cartons etc. contained in current WIs and SOPs would include linerless cartons and their blanks and lids. In general, current WIs and SOPs were broad enough to incorporate the use of linerless cartons with little modification. However, certain sections would benefit from the inclusion of specific reference to linerless cartons. For example, carton blank receival and storage, carton forming and lidding operations.

#### 4.4.4 GMP for the handling, storage and use of linerless cartons

The following flow chart and HACCP table highlight the critical stages in the handling, storage and use of linerless cartons and detail steps that need to be taken to control/minimise contamination. Current information on carton quality is based on the use of virgin card for the manufacture of carton blanks and lids. Re-cycled fibreboard may impact on the risk of contamination of product and should be further investigated before being considered for use.

Flow Chart	t for Linerless C	artons	
Carton Blanks On arrival check pallets for any	Receiving	Lid Blanks On arrival check for any damage	
damage to packaging and/or signs of gross contamination		and/or signs of contamination. Pallets must be wrapped with top and bottom cardboard caps.	
Store palletized blanks in dry store. Transfer to carton room under hygienic conditions as needed. Part-	Storage	Store palletized blanks in dry store. Move hygienically to lidding machine. Part-used pallets stored in	
used pallets are stored hygienically with the top blank positioned such that its coated surface is contacting the coated surface of the next blank.		dry store. Part-used pallets stored in dry store. Part-used pallets are stored hygienically with the top blank positioned such that its coated surface is contacting the coated surface of the next blank.	
Load blanks into base erector on trolley supplied (discard top blank from part used pallets). Ensure that blanks remain covered when not in base erector. Store formed cartons contact surface side down to avoid contamination of liner surface.	Base Assembly		
Packing operations in boning room as per current SOPs. Care to avoid contacting liner with hands. Ensure that all meat is within the carton.	Packing		
Exposed meat does not contact non- food contact surfaces during handling.	X-ray		
Monitor process to ensure that glue does not contaminate meat	Carton Closure	Load blanks into lidding machine (discard top blank from part-used pallets). Coated surface must not contact non-food contact surfaces. All contact surfaces must be washed and sanitized daily or when visibly contaminated.	
Follow current SOPs. New SOPS for handling damaged cartons	Freezing and Storage		

Hazard Analysis/Preventative Measures Linerless Carton					
Process Step	Hazard	Preventative Measure			
Receiving	Biological contamination due to exposure of lined blank surfaces to environment. Physical contamination of blanks with fiberboard	<ul> <li>Blanks are capped top and bottom and double wrapped</li> <li>Visual inspection made of integrity of packaging on receipt of palletized product.</li> <li>Manufacturing process (Visy) monitored by Visy for physical contamination. If necessary mitigation strategies (blowers) will be installed</li> <li>Physical contamination monitored at the processor on opening of pallets</li> </ul>			
Storage	Biological contamination from the environment and/or insects and pests.	<ul> <li>Dry store maintained free of obvious dust and contaminants</li> <li>Dry store covered under company's pest control program</li> <li>Monitor palletized blanks for signs of contamination</li> </ul>			
Base Assembly	Biological contamination from the environment Physical contamination with fiberboard	<ul> <li>Pallets are not unwrapped until they are in the carton room</li> <li>Any unused blanks are wrapped and stored in the carton room until used or discarded (top blank turned over so that coated surfaces are in contact)</li> <li>Handwashing facilities are available in the carton room for staff</li> <li>Carton room kept clean and free from obvious dust and contamination</li> <li>Monitor assembled cartons for signs of fiberboard contamination</li> <li>If necessary install a blower/vacuum system to remove fiberboard contamination</li> <li>Invert and tap formed cartons to remove large pieces of fiberboard if present</li> </ul>			
Packing	Hazards controlled as per current boning room CCPs	<ul> <li>No additional controls for linerless cartons needed at this step</li> <li>Limit hands contacting coated surfaces</li> <li>Insure that meat is all within the carton</li> </ul>			
X-ray	Biological contamination of meat entering the X-ray machine	Ensure that non-food contact surfaces do not contact product			
Carton Closure	Biological contamination from environment	<ul> <li>Environment kept clean and free from obvious dust and contamination. Room refrigerated, and hand washing facilities are available</li> <li>Lined surface of the lid blank only contacts clean, stainless steel surfaces prior to entering the lidding machine</li> </ul>			

	Physical contamination from overhead equipment, including grease as oil	• Exposed meat surface protected from overhead contamination by ensuring that conveyor system is covered in critical contamination areas.
Freezing and Storage	Biological contamination from environment if cartons are damaged	<ul><li>Rework policy for damaged cartons</li><li>Monitoring of carton integrity</li></ul>

# 4.5 Carton integrity

#### 4.5.1 Domestic trials

Cartons were assembled at Visy Brisbane and transported, wrapped to the processing plan where they were packed with normal product for production runs to a local grinding facility and one located interstate.

#### 4.5.1.1 Local Grinding Facility

Five pallets (180 cartons) were packed at the processing plant in February 2017, using prefabricated linerless cartons supplied by Visy. Product was transported by road to the grinding facility located approximately one-hours' drive from the processor. The time between packing and opening was approximately 5-days.

Carton integrity was satisfactory on arrival and cartons were opened in the production area without tempering. Initially there were issues with opening cartons as operators were not familiar with the techniques required (Fig. 4).



Fig. 4 Operator initially struggling to open a linerless carton

There was some delamination of the liner where it contacted glue on the lid, but this was not considered a contamination risk (Fig. 5).



Fig. 5 Carton de-lidded showing delamination of the liner on the where it contacted glue on the carton lid.

Once operators became familiar with the cartons and developed their own opening technique, deboxing proceeded without issue (Fig. 6).



Fig. 6 Linerless carton after emptying showing intact packaging (white areas are ice crystals).

Management at the grinding facility were happy with the trial outcomes, although there was some concern with the recyclability of the cartons. Currently cartons are 97% recyclable, while the grinder requires 100% recyclability.

#### 4.5.1.2 Interstate grinder

Five pallets (180 cartons) were packed at the processing plan in March 2017, using prefabricated linerless cartons supplied by Visy. Product was transported by road to the facility in Sydney. There was approximately 5-days between packing and carton opening at the grinding facility.

Three cartons were damaged during transport and associated product discarded. It is likely that, for at least one carton, similar damage to a lined carton would also have exposed product (Fig. 7). The integrity of the remaining 177 cartons was satisfactory.



Fig. 7 Carton damage during transport from the processor in Queensland to a grinding facility in Sydney.

Cartons were tempered for approximately 2 ½ days to -5°C prior to opening. It was noted on opening that cartons had slightly degraded due to moisture penetration of the outer cardboard layer during the tempering process. However, there was no loss in carton integrity. Visy will undertake further trials of the effect of tempering on carton integrity.

Cartons were opened using a spatula, purpose-built tool or knife (Fig. 8).



Fig. 8 Opening of linerless cartons after tempering using a commercially available spatula (a), purpose-built tool (b) or knife (c).

All opening techniques worked satisfactorily, although opening with a knife was preferred due to possible repetitive strain injury (RSI) concerns with the other techniques. Use of a knife could result in contamination of product with cardboard dust if both the lid and carton wall are cut. Care needs to be taken to ensure that only the lid is cut during opening. Operators reported that the linerless cartons were easy to open and separate from product. Visy have prepared a guide for opening cartons which is summarised in Appendix 2 of this report.

There was no evidence of delamination because of tempering. Some purge fluid was noted in the bottom of the cartons, but no leakage to the outer carboard layer was observed. One carton had been assembled using a traditional lid, which resulted in contamination of the meat surface with cardboard. The product in this carton was re-worked and including in the production run. It may be necessary to identify linerless lids in some way so that this does not occur in the future.

Management at the grinding facility were generally happy with the trial. There were questions raised about temperature and microbiological monitoring of linerless cartons and how this could be effectively carried out without prematurely exposing product.

#### 4.5.2 International trials

Prior to commencement of international trials linerless carton operations were shifted from the original processing plant to another processing plant. This move was undertaken because it was felt that the linerless project was better suited to the second facility's design and throughput. Linerless cartons were still assembled at Visy's Brisbane facility and transported by road to the second plant for the international trials.

The following summarises feedback from the processing company staff and customers on-site in the US.

Seven containers (4,184 cartons) were packed at second plant and shipped under normal commercial conditions to the US where the port-of-entry (POE) was Philadelphia. No shipping details were reported. Two containers were inspected by the FSIS at the cold store, while the remaining 5 loads were inspected at the another cold store. Four cartons in the firstcold store lot were rejected by the FSIS due to exposed product because of carton damage (0.1% of total trial number of trial cartons presented at POE).

One container (696 cartons) from the cold store was sent to further processing at grinder A while the other (700 cartons) was sent to grinder B for processing. The five containers at the other cold store were sent for processing at one of three other grinding facilities (C, D and E).

#### 4.5.2.1 Grinder A

The processing company staff were present during the operations at Grinder A. A full report of their visit is provided in Appendix 3 of this report. The container of linerless cartons was delivered to grinder A in April 2018. On arrival at the grinder, two cartons were observed to be damaged, exposing product; product was re-worked and processed normally under the grinders own SOPs. There was no reason given for the observed damage. Cartons were tempered from -18°C to -5°C by microwaving individual cartons with the lid on. Product was re-palletised after tempering. Some softening of the outer carboard layer was observed after microwaving but the integrity of the cartons was not compromised. As with previous trials initial de-boxing, prior to any operator training, resulted in some cardboard residues adhering to the meat surface (Fig. 9).



Fig. 9 Cardboard stuck to meat surfaces in de-boxed linerless carton meat.

Contaminated product was re-worked and processed normally. One carton in the initial pallet processed had a non-lined lid. This was identified as a potential issue during the domestic trials; corrective actions are being investigated. Once staff had been trained in the proper technique for opening linerless cartons the de-boxing process proceeded without issue. While freezer burn was not raised as an issue by the grinder there was some evidence of dehydration on the upper surface of some cartons. Management at the facility were generally happy with the linerless cartons.

#### 4.5.2.2 Grinder B

The processing company staff did not attend the opening of the 700 cartons sent to grinder B in June 2018. Cartons were tempered to -5°C in a microwave with lids removed. There was a slight issue with requiring an extra person to aid with flipping the boxes after tempering. This was basically a product flow issue and should be able to be addressed. In general, management at the facility were happy with the quality of the linerless cartons, no other feedback was provided.

#### 4.5.2.3 Grinders C, D and E

Cartons in the five containers from the other cold store (3,484 cartons) passed POE inspection and were sent to one of three grinding facilities. No carton damage was reported at the grinder. No feedback has been provided from these facilities except to say that no problems were encountered either with the integrity of the cartons or with their de-boxing.

# 5 Discussion

#### 5.1 Chemical risk assessment

Most of the compounds reported in the Rutgers (2016) study are typically found in recycled paperboard (Rutgers 2016). Therefore, it is difficult to interpret the significance of the findings of the study without some baseline information. A similar study using traditional liners would allow a

better estimation of the risk posed by linerless cartons. Nevertheless, overall extractables reported in the Rutgers (2016) study for films used in linerless cartons were below the required FDA limit. Key compounds identified in the Rutgers report were either below the FDA threshold of regulation (TOR) or EFSA threshold of toxicological concern (TTC) or are below published total dietary intake (TDI) where these limits have been published. While BPA was detected the level found was below published regulatory limits.

Based on the migration study it is unlikely that chemicals of concern will migrate from linerless cartons to meat in sufficient concentrations to pose a health risk to consumers.

# 5.2 Physical risk assessment

The adhesive tape surface cleanliness test appears to be a fast and reproducible method for the visualisation of physical contaminants on contact surfaces. However, contamination of surfaces during sampling is a possibility. It is recommended that this technique be adopted, in addition to a visual inspection of cartons for fibreboard off-cuts, as part of the company's QA program and that appropriate action limits are set.

Based on the findings detailed in this report the current level of physical contamination on the contact surfaces of linerless cartons is similar to that observed on plastic liners and should not pose a risk to consumers.

# 5.3 Microbiological risk assessment

While some published studies (Hladíková et al 2004, Namjoshi et al 2009) have shown large numbers of microorganisms contaminating fibreboard there is a paucity of information on the contribution of such contamination to the overall bacterial load on food, especially when such material is lined. The relative low numbers of bacteria found on linerless cartons and normal liners in the present study would suggest that packaging plays little role in determining the final level of bacterial contamination on meat. There have been no reported cases where microorganisms migrating from packaging material to foods have resulted in human illness, and for raw foods, such as meat, the food rather than the packaging is the dominant source of microbial contamination (Wirtanen and Salo 2007).

Petrifilm is a suitable method for the on-going monitoring of microbial contamination on linerless cartons.

# 5.4 Review of WIs and SOPs

Most of WIs and SOPs relating to the handling and storage of packaging are generic enough to incorporate linerless cartons, however some need to be reviewed to ensure that they include specific refence to linerless carton. Additional WIs may be required to elaborate on specific issues relating to the handling and storage of linerless carton blanks and lids as these products are essentially food contact surfaces. Key areas that should be reviewed are transport and storage of blanks, additional steps in carton forming and potential contamination of cartons and lids during the lidding operation. Of concern is the transport and storage of carton blanks. Current practice leaves palletised carton blanks outside the processing area where there is the potential for contamination even though the pallets are wrapped. It is recognised that the lidding operation poses a potential

source of contamination of product and that the process requires re-engineering of the current conveyor system.

It was difficult to detail specific handling and storage requirements as the base erector has not yet been installed at the plant and therefore 'normal' practices have not been in operation. Once all equipment has been put in place and is in routine use, a review of the companies HACCP plan should be carried out with specific reference to linerless cartons.

# 5.5 Carton integrity

Trials looking at the integrity of linerless cartons under commercial conditions followed similar patterns. While damage to linerless cartons appeared similar to that of traditionally packaged product it was not clear if product integrity was compromised to the same degree. Four cartons were rejected at POE (0.1% of total number of trial cartons presented at POE), this was similar to the 2016-17 rejection rate of 0.23% reported for similar product. It is likely that damage to linerless cartons will result in more exposure of product than damage to traditional cartons, although without more data the impact of this cannot be determined. Companies wishing to use linerless cartons should obtain accurate historical data on rejections and disposition to allow comparisons to be made.

On two occasions non-lined lids were used to seal linerless cartons resulting in contamination of product on opening. It is not clear how this occurred but to avoid such incidences in the future lined lids should be clearly identified. Visy should investigate possible changes to the printing of lids to incorporate some identifying mark.

Softening of cartons was noted after tempering due to moisture migration to the fibreboard layer. While this did not result in loss of carton integrity it may be an issue particularly where cartons are re-palletised after tempering. More work on the effect of tempering on the linerless cartons is needed before the significance of this can be properly estimated.

At the trials where detailed feedback was provided, it was clear that initially there were issues with opening cartons without contaminating product. However, in all cases this was due to the technique being used and once corrected, linerless cartons were de-boxed without issue.

While there was no negative feedback from customers in relation to freezer burn (dehydration of product surfaces during frozen storage), it was noted on opening of some linerless cartons in the international trials. Excessive freezer burn can have economic impacts and increased risk of the development of rancid flavours in meat. The incidence of freezer burn should form part of any on-going monitoring of the quality of product packaged in linerless cartons. Visy should investigate possible intervention for the control of freezer burn in linerless cartons.

# 6 Conclusions

The results of this work support the integration of linerless cartons into Australian processing facilities. However, such cannot proceed without gaining:

• acceptance of the risk assessments by the department,

- an alternate compliance approval from the departments' published policy on the use of linerless cartons;
- approval of amendments to the appropriate sections of the approved arrangement as recommended by this report; and
- appropriate equivalence agreements with key markets.

# 7 Key messages

- Linerless cartons do not present any greater risk to consumer health than conventionally lined cartons and offer greater protection from physical risks such as poly-entrapment
- The integrity of linerless cartons during distribution and storage is similar to conventional systems
- Approval for use of linerless cartons is required by markets

# 8 Bibliography

AS 3724 – 1994. Fibreboard boxes for the export of meat, meat products and offal.

AS 5013.1 (2004). Examination for specific organisms – Standard Plate Count.

Bhunia K, Sablani S, Tang J, Rasco B, (2013) Migration of Chemical Compounds from Packaging Polymers during Microwave, Conventional Heat Treatment, and Storage. *Vol.12,2013 Comprehensive Reviews in Food Science and Food Safety*, **12**, 523-545.

COEH (2016) Proposition 65 No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity'. Californian Office of Environmental Health Hazard Assessment.

EFSA (2005) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to Bis(2-ethylhexyl)phthalate (DEHP) for use in food contact materials. European Food Safety Authority.

EFSA (2009) Toxicological evaluation of benzophenone. EFSA Journal 1104, 1-30.

EFSA (2012) Scientific Opinion on Mineral Oil Hydrocarbons in Food. *EFSA Journal* **10**, 2704-2889. <u>https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2704</u> (verified 2 August 2018).

EFSA/WHO (2016) Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. Available at <a href="http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1006/pdf">http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1006/pdf</a>. (verified 2 August 2018)

FDA (2007) Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations. Available at

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Ingredi entsAdditivesGRASPackaging/ucm081818.htm. (verified 2 August 2018)

FDA (2008) Draft assessment of Bisphenol A for use in food contact applications. Available at <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008\_0038b1\_01\_02\_FDA%20BPA%20Draft%2</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018</a> <a href="http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018">http://www.fda.gov/ohrms/dockets/AC/08/briefing/2018</a> <a href="http://www.fda.gov/ohrma/dockets/AC/08/briefing/2018">http://www.fda.gov/o

FSANZ (2016) Proposal P1034 - Chemical Migration from Packaging into Food. Supporting document 3 – Risk Profile. Available at

http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingin toFood.aspx. (verified 2 August 2018)

Hladíková Z, Kejlová K, Sosnovcová J, Jírová D, Vavrouš A, Janoušek A, Syčová M, Špelina V, (2015) Microbial contamination of paper-based food contact materials with different contents of recycled fibre. *Czech Journal of Food Science*, **33**, 308–312.

ISO 8502-3 (1992) Preparation of steel substrates before application of paints and related products — Tests for the assessment of surface cleanliness — Part 3: Assessment of dust on steel surfaces prepared for painting (pressure-sensitive tape method).

Meat Standards Committee, (2002) Microbiological testing for process monitoring in the meat industry, Guideline.

https://www.primesafe.vic.gov.au/uploads/Victorian%20Standards/Microbiological%20Guidelines Meat.pdf (verified 2 August 2018)

Namjoshi K, Johnson S, Montello P, Pullman G S, (2009) Survey of bacterial populations present in US-produced linerboard with high recycle content. *Journal of Applied Microbiology*, **108**(2), 416-427.

Pocas M, Hogg T, (2007) Exposure assessment of chemicals from packaging materials in foods: a review. *Trends in Food Science and Technology* **18**, 219–230.

Rutgers (2016) Regulatory Compliance Testing of Visy Industries Blue Linerless Carton. Mass Spectrometry Laboratory Report #6726. Mass Spectrometry Facility, Centre for Advanced Food Technology. Rutgers, The State University of New Jersey, USA.

SCENIHR (2015) Opinion on the safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk. Scientific Committee on Emerging and Newly-Identified Health Risks.

Wirtanen G and Salo S, (ed) (2007) Microbial contaminants & contamination routes in food industry. 1<sup>st</sup> Open seminar arranged by Safoodnet - food safety and hygiene networking within new member states and associated candidate countries, Espoo, Finland.

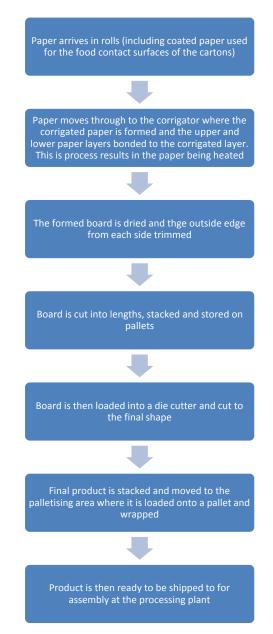
https://www.vtt.fi/inf/pdf/symposiums/2007/S248.pdf (verified 2 August 2018)

# 9 Appendices

# 9.1 Appendix 1 – On-Site Inspection of Visy Manufacturing Facilities

The following report relates to the on-site inspection of Visy facilities at Yatala and Hemmant undertaken on the 10<sup>th</sup> October 2016. The notes reflect impressions of the facilities and equipment as well as discussions on the day.

Manufacture and assembly of the linerless cartons is a critical step in controlling possible contamination of cartons and the subsequent contamination of product. A brief schematic of the manufacturing process is given below.



There are opportunities for fibreboard to become contaminated during the manufacturing process. Raw materials (rolls of paper, including coated paper) are stored open to the environment and are clearly contaminated on the outside edges prior to manufacture into fibreboard. This contamination

is unlikely to pose a risk as the manufacturing process includes a heating step that is sufficient to inactivate microbes of concern i.e. enteric pathogens. There may be issues with spore forming bacteria. Further, contaminated outer edges are removed from the formed fibreboard prior to cutting into lengths. The greatest potential source of contamination during the manufacturing process is environmental contamination during storage of fibreboard sheets prior to cutting and packaging. There was no indication of dust on stored product on the day and the manufacturing floor in general was clean. A potential source of contamination was open windows in the manufacturing area. This could allow dust or pests to enter the factory from the external environment. The risk of contamination can be minimised by sealing these windows or by covering the fibreboard sheets during storage with a plastic sleeve.

After cutting product is palletised. There is potential for the upper and bottom surface to be contaminated during this process either from the pallets or from airborne contamination of the top carton blank. To mitigate this risk, it is recommended that an upper and lower cap be fitted to the stack of blanks prior to final wrapping. Once the product is wrapped there is no further opportunity for contamination unless the wrapping integrity is compromised. Checks of packaging integrity should form part of the processor's standard operating procedures.

An inspection of the base erector at the Visy Hemmant facility was also undertaken. This equipment will eventually be installed at the processor. There is potential for contamination of the inner liner of the carton blanks during assembly. This can be minimised by effective cleaning of the base erector and in particular the stainless-steel plates that contact the inner surface of the cartons during assembly. The top of the unit is currently opened to the environment and this could provide a potential route for contamination of the inner carton surface. It is recommended that the top of the base assembler be sealed to prevent potential contamination and cleaning protocols established. Control of cross-contamination in the base erector will need to be addressed at the processing plant. There is the possibility for glue to contaminate food contact surfaces, although this is unlikely given the configuration of the glue spray jets. Monitoring of potential glue contamination on food contact surfaces should be carried out at the processor during routine operation. Exposure of carton blanks during the assembly process should be minimised and this should be addressed in the carton assembly SOP.

# 9.2 Appendix 2 – Visy carton opening SOPs

# 9.2.1 Handheld stainless square head

#### Step 1

Step 2



- Place lead edge on stainless implement under the long lid flap of the MC linerless base and move from one side to the other and also along both short side lid flaps.
- Hinge lid on back long edge.



• Either by hand or implement, pull open the 2 triangular glue flaps on the long panel of the MC linerless carton.

Step 3



• As above.

#### Step 4



• Hinge lid on back long panel and hand pull the exposed long panel at either end on the triangular shaped glue flaps.

Step 5



• Frozen trimmings will come away from MC linerless base very easily.

#### 9.2.2 Spatula

#### Step 1



- A spatula can also be used in the same way as the previous stainless implement.
- Place lead edge on stainless implement under the long lid flap of the MC linerless base and move from one side to the other and also along both short side lid flaps.
- Hinge lid on back long edge.





• Either by hand or implement, pull open the 2 triangular glue flaps on the long panel of the MC linerless carton.

#### 9.2.3 Knife

#### Step 1



• Set Stanley knife to a depth of 8mm and run the knife edge along one long panel and the 2 short panels at about 5mm from the top.

#### Step 2



• As above.





• Hinge lid on long back panel.

Step 4



- Hand pull exposed long panels at either end of the triangular glue flaps.
- Frozen trimmings will come away from MC linerless base very easily.

# 9.3 Appendix 3 –linerless carton trial performance report

#### BACKGROUND

The processor partnered with Visy Australia to pack frozen beef trim into "Linerless" cartons. A total of seven loads were packed off at the processor.

Two containers were packed for USA, with 700 cartons delivered to Site A and 700 to Site B. The remaining five loads were consigned to an importer to be delivered to a Grinders.

#### AIM

To provide a Linerless option to the market that has been trialed, which can meet supplier, customer and market expectation.

#### **EXECUTIVE SUMMARY**

Port of entry was Philadelphia. Two loads to Cold Store A and five to Cold Store B. Four cartons in the Cold Store A loads were refused entry for carton damage. All cartons at Cold Store B were cleared for entry.

First load was delivered to Site B on the 25<sup>th</sup> April 2018. Two cartons had damage where product was exposed. There were no other damaged cartons reported in this load. Exposed product was reworked and used.

First pallet of thirty-five cartons were tempered (microwave) then transferred for grinding. No implements are used to assist with de-cartoning. Four cartons had large strips of linerless paper stuck to meat. Linerless paper was removed prior to releasing product for grinding. It was noted that the cause of this was the technique used by operators during de-cartoning.

Second pallet was delivered; we requested if we could demonstrate de-cartoning technique. Thirtyfive cartons were de-boxed with one 5mm piece of paper stuck to meat. This was due to operator error. Paper was removed, and product released for grinding.

Post training of personnel in preferred de-cartoning method the remaining cartons were processed with no further issues.

Objectives achieved: (1) able to de-carton product without the risk of paper being stuck to meat, (2) able to keep up with line speed (3) able to maintain separation of carton and product handling with one person (4) able to perform task without the use of a knife or implement.

#### LINERLESS REVIEW – CARGILL (BUTLER, WISCONSIN)

Senior management commitment

Traci (GM)/Joel (OPS) – Site induction; including safety focus, production capabilities, brief history (facility), key performance objectives

Site tour

Joel/Mike/Broader team - Plant tour of North and South plant operations

#### Primary Process

- Product is stored in on-site freezer stores operated by third party.
- All product passes through a microwave (single carton). Product is tempered from -18°C to ~-5°C to assist with grinding. Product is re-palletised post tempering. It was noted that cartons did appear wet post tempering. Further testing, by Visy, would need to analyse any potential risk associated with paper degradation/delamination post microwave/tempering.
- Palletised product is transferred to the primary grinding station. At the time of the trial Site B were using another trim (with liners) and processor (linerless).
- Product is de-cartoned by tearing the lid off the carton. No implements are used during this process. We observed some minor poly entrapment in another trim. An implement is used to remove entrapped poly from trim (*Grinders procedure*).
- First pallet of linerless product was inspected prior to transferring to elevated platform. There were two cartons with damage where product was exposed. Site were unable to explain where damage may have occurred. Product was reworked and used (*Grinders procedure*).
- Pallet was transferred to de-cartoning station. Operators commenced tearing lids off cartons. There were four instances where linerless paper tore and remained stuck to meat. All paper defects were removed, and product cleared for grinding. As more care was required production was slowed to reduce any possible risk of paper entering the primary grind. It was noted during de-cartoning of the first pallet; due to the technique used to remove the lid, where glue was stuck to linerless paper on the base and lid, the paper could tear. Furthermore; it was possible that during tempering water vapor may form between the linerless lid and meat. Cartons are then stacked on top of each other as product is repalletised. As product is still at -5°C vapor may refreeze bonding meat to linerless paper.
- There was an isolated case of a normal lid (non linerless) being applied to trim. This resulted in cardboard being stuck to meat. Product was reworked and cleared for grinding (Grinders procedure). Other considerations:
  - Freezer burn: some signs of freezer burn (dehydration) were observed. Further investigation, by Visy, must be completed over time and include any change in flavor profile due to oxidation.
  - Base glue patterns: It was noted that triangular folds on the long edge of the carton were popping. Visy need to review and improve/increase glue to these four areas of the carton base.
  - Packing: It was noted that if product is not packed flat voids are created inside the carton. As the compactor is not used in this process, packers must ensure product is

packed flat. Voids become an issue when product is stacked on top as there was nothing supporting the lid making it more likely for damage to occur.

- Second pallet we requested if we could demonstrate de-cartoning technique. It was explained that we would be (1) able to de-carton product without the risk of paper being stuck to meat, (2) able to keep up with line speed, (3) able to maintain separation of carton and product handling with one person (4) able to perform task without the use of a knife or implement. Due to one minor error in technique we had one minor 5mm piece of paper stuck to meat. We were able to meet all other expectations. Paper was removed and cleared for grinding (Grinders procedure).
- The remaining product was processed by site after training with personnel. No other defects were reported.

#### SUMMARY

Based on positive result of this and other "Linerless" trials we recommend this product to be fit for purpose as a linerless product. It is understood that Visy must supply the processor with instructions on the removal methods for linerless trim. These may include manual, use of implement or knife and can be supplied to customers for training purposes. Visy shall conduct further trials to provide answers to additional issues raised as a result of microwave tempering.

Butler are currently using other linerless cartons containing FTM 50CL product. The major difference is this liner is clear. We were able to view the process at Cargill (Schuyler). FTM product is separated injected with CO2 and formed using a press. As product is partially frozen once it is inserted into the linerless base the product is a perfect shape (cube). As the product is already frozen the product comes free from the linerless product easily.

Visy have provided all bases and lids for all trials to date. These have been pre-formed at Visy Technology Hemmant then transported to processing facilities for use. The base erector is a prototype, though can be setup for use in full production. During the trials the processor used the current rotary lidder. Consideration should be made to replace the current Visy lidder and prototype base erector.