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Submission on Proposal P1034: Chemical Migration from Packaging into Food

The Vinyl Council of Australia is the peak association for the vinyl, or PVC, industry in Australia. Our members include both local manufacturers and importers of products - companies committed to advancing the quality and sustainability of their products.

A number of our members manufacture PVC food contact materials or supply raw materials and intermediates to such manufacturers. PVC, or vinyl, is used in both flexible packaging films and rigid containers. It is also used in food processing equipment such as hoses.

The flexible properties for some PVC applications is derived from the use of plasticisers. A wide range of substances are used today as plasticisers including Epoxidised Soy Bean Oils (ESBO), other food oils, citrates, ortho-phthalates (DINP, DEHP etc), terephthalates and alternatives (see Appendix).

We are interested in the Proposal, in particular the reference to the use of phthalate plasticisers in food packaging and offer the following comments reflective of the PVC industry in Australia.

We understand that FSANZ believes there are some gaps in current risk management related to Chemical Migration from Packaging into Food (CMPF) and the Proposal aims to determine measures required to manage the food safety risks arising from CMPF in Australia and New Zealand.

We agree with FSANZ's assessment that overall in both Australia and New Zealand, the risks from CMPF are low as estimated exposures to packaging chemicals detected in foods and beverages have been found to be below internationally recognised safe levels. It is therefore essential that any changes to existing measures to manage risk are appropriate and proportionate.

Decisions to amend the current measures should be based on sound scientific evidence with appropriate margins of safety. The challenge of applying the 'Precautionary Principle' is that an absence of risk cannot be proven, or the converse: it cannot be proven that anything is 100% safe.

Based on the information presented in the Proposal, many in the vinyl value chain are of the view that, of the four risk management response options proposed, maintaining the status quo is currently justified.

As the Proposal reports, local packaging manufacturers and raw material suppliers show good awareness and uptake of international packaging regulations. Feedback in the vinyl sector suggests that major food packaging manufacturers are aware of their responsibilities when it comes to migration and contaminants into the packaged food and as such, take measures to ensure this is not occurring.

It is estimated that imported films now represent more than 20% of the Australian market and these are imported from a range of countries and producers. Their quality and consistency varies. Many are cast films, which are highly plasticised. This higher plasticisation increases their global migration levels.

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A key local food contact material supplier has advised that their customers regularly conduct migration testing into their food products and find negligible levels of any contaminates, including phthalate plasticisers. They also point out that they have been using these material formulations for many years with a good performance in terms of risk of migration of chemicals into their food. The supplier has reported that its customers wish current Codes and regulations with respect to CMPF to remain the status quo.

Nevertheless, we offer some additional considerations below.

DEHP and DINP plasticiser migration

FSANZ has identified the plasticisers, DEHP and DINP, used in PVC materials but also printing inks and other packaging related materials, as two chemicals that may present a higher risk to consumers based on a recent limited surveillance study.

FSANZ found that additional food concentration data are required to determine if dietary exposure to these phthalate plasticisers poses a health risk and is now undertaking a study to acquire data.

DINP poses a low health risk

FSANZ's Proposal suggests that the Graduated Approach may offer the most advantages in terms of protection of public health and safety and cost effectiveness and presents a draft framework in the Proposal. Under this, Low Risk chemicals would be characterised.

DINP, a high molecular weight ortho-phthalate, is not classified as hazardous. It should be noted that NICNAS has recently assessed and reported that "the public health risks for the general population (without occupational sources) and children (with or without mouthing toys) from all exposure sources (including indirect exposures via the environment) to [DINP] are … considered low, based on the evaluation of margins of exposure (MOEs)"[1].

In Australia, DEHP- a low molecular weight ortho-phthalate - is restricted for use in toys and childcare articles and cosmetics following completion of a risk assessment by NICNAS in 2010, which found a potential risk of reproductive developmental toxicity for babies and children based on worst case exposure scenarios. General use of low molecular weight ortho-phthalates is diminishing in Europe driven by hazard classification and restriction of use under REACH. It is no longer used in locally produced vinyl food contact packaging films (see below).

Risk mitigation via Standards and Industry Codes

One criteria in the proposed characteristaion of Low Risk chemicals in the Graduated Approach is that the chemical is well managed through risk mitigation measures, including: evidence of compliance with AS 2070-1999, EU and/or US regulations, and/or Codes of Practice.

EU Plastics Regulations 10/2011 allow these phthalates to be used as plasticizers in repeat use materials or materials contacting non-fatty foods and having to meet their respective specific migration limits (9mg/kg for DINP and 1.5mg/kg for DEHP). However, it has been reported to the Vinyl Council that adequate testing facilities do not currently exist in Australia for films to be tested routinely in a similar fashion as to that which occurs in Europe.

[1] Inventory Multi-Tiered Assessment and Prioritisation (Imap) Human Health Tier II Assessment, NICNAS 2014

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There are currently no barriers preventing importers bringing in food contact film, regardless of whether it complies to AS2070 or not, and regardless of the type of plasticisers used, or the level of plasticisation. The industry would like to see this addressed and there is potential scope to develop a global migration limit in relation to packaging films.

If AS2070 remains as the primary measure, then all products should be required to state compliance through specific labelling on the product (or primary carton). If products are subsequently found not to comply, the ACCC would be expected to take action.

Chemicals falling within the category of low risk could be managed through the use of voluntary industry guidelines.

In the late 1980s, the Australian PVC food contact packaging film industry adopted a voluntary Industry Code of Practice (ICP) whereby their films were colour-coded to indicate appropriate food-group use and formulated accordingly to minimise chemical migration risk:

Use	Film Colour	Plasticiser
For vegetables	Green	Di-ethylhexyl phthalate (DEHP)
For meat	Natural (Champagne)	Di-octyl adipate (DOA)
Catering, deli & food service	Blue	Polymeric plasticiser/DOA mixture

This voluntary code in effect tightened the Australian Standard for Plastics and Food Contact, AS 2070, with which all Australian-made films comply. However, the ICP is now out-dated as DEHP and polymeric plasticisers are seemingly no longer used in locally produced vinyl food contact films so the need for colour coding of films today has reduced.

The Industry Code is therefore currently being updated and incorporated into the vinyl industry's PVC Stewardship Program (see http://www.vinyl.org.au/sustainability/pvc-stewardship). The new ICP will restrict the use of ortho-phthalate plasticisers such as DEHP and DINP in vinyl food contact packaging films.

Under the PVC Stewardship Program, packaging film manufacturers will be required to report compliance with this Industry Code and may be audited periodically. The new Code is expected to be published before the end of 2016, and could be incorporated into a guideline for PVC food contact packaging films under the FSANZ Proposal.

Conclusion

- The local vinyl packaging industry is confident that the risk of chemical migration from packaging to food is well understood, managed and controlled.

  However, there is concern that producers of imported materials may not have the same level of management or control.
- Any changes to existing measures to manage risk should be appropriate, proportionate, cost effective and based on sound scientific evidence.
- Scientific studies show that high molecular weight ortho-phthalate plasticisers such as DINP pose a low health risk to the public and their use is well managed. As a low risk chemical specific migration limits may not be warranted.
- Based on the information presented in the Proposal, many in the vinyl value chain are of the view that maintaining the status quo is currently justified in respect of vinyl materials. Nevertheless, adoption of a new voluntary Industry Code of Practice

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for vinyl food contact packaging films presents an opportunity to incorporate it into a guideline under the Graduated Approach.

- In addition, industry would welcome stronger enforcement of adherence to AS2070 including mandatory labelling of compliance to the Standard.

Yours sincerely

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Appendix

Regulatory Situation for Plasticisers in Australia

Low Molecular Weight	High Molecular Weight	Non-Phthalates
Assessed: DEHP (2010), DEP (2011), DBP (2013), DMP (2014), DMEP (2014), BBP (2015)	Assessed: DINP (2012 & 2014), DIDP (2015), DnOP (2015)	NONE Assessed Examples: DINCH, DOTP, adipate esters, ESBO, bio-based plasticisers
NICNAS Recommendations Add to Appendix C of Poisons Schedule for use in: -Cosmetics and personal care products (DEHP, DEP, DBP, DMEP, BBP) -Toys: DEHP *Note: No restriction of DEHP in medical products*	No restrictions on use	No restrictions on use

Regulatory Situation for Plasticisers in Europe

CLASSIFIED PLASTICISERS
Category 1B - toxic for reproduction
REACH Candidate List

Orthophthalates
Low molecular weight 3-6C
DEHP* DBP*
DIBP BBP
DPP DIPP PIPP
DIHP 711P DMeP
DHxP DnHxP

DCHP

**ECHA recommends Authorisation for Deza, Grupa Azoty and Arkema – selected applications*

NON-CLASSIFIED PLASTICISERS
Not on REACH Candidate list

Orthophthalates
High molecular weight ≥7C
DINP DIDP DPHP

Sebacates
DMS DBS

Azelates
DIDAz

Trimellitates
TOTM

Citrates
ATBC

Cyclohexanoates

Terephthalates
DOTP DBT

Adipates
DEHA DINA
DIDA DTDA

Phosphate Esters TPP

Dibenzoates
ODEDB OXPDB

Vegetable oil based
ELO ESBO H. Castor oil

Benzoates
INB IDB

Note: *some members of above families may not be REACH registered nor evaluated for classification or risk assessed*