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Food Standards Australia New Zealand (FSANZ)
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Subject: Submission on Proposal P1034 Chemical Migration from Packaging into Food

1 Introduction

NCI Packaging manufactures metal food cans in New Zealand (NZ) and Australia, and plastic food containers in Australia (A). NCI considers that if any changes are made to the AS/NZ regulations that they reinforce and define the applicability of the USFDA and EU regulations.

2 Submission Main Points

A. if changes are made to the standard, they need to specifically highlight the different packaging types, as currently the regulations are only explicitly for plastic. People just use these standards for other materials, such as in our case metal, as there isn't anything else to use.

B. Section 1.4.3 isn't really relevant for safety of the food, only implements used for eating. This should probably be listed elsewhere in the wider regulations.

C. In preference to measuring the contaminants listed in section 1.4.1 we usually ask for assurances that these materials are not intentionally added to the packaging (or coating in our case). Internationally PCB's are a lot less relevant than in the past and we think requirements on them could be removed. There is not much likelihood of PCBs being present in food contact surfaces now. PCBs are mentioned in the USFDA 21CFR 109.15 as well.

D. If changes are proposed to the standard, we feel that defining what aspects of packaging are the most important for food contact safety is needed. New Zealand doesn't need a new guideline, we can just pick the best bits out of the US and EU regulations as I've done below. There is a lot of commonality between FDA and EU.

• General suitability of coating with food	21CFR 170 and EU 1935/2004
• Suitability of raw materials	21CFR 175.300 and ResAP(2004)1
• Prohibited materials	21CFR 189 and (EC) No. 1907/2006
• Good Manufacturing Practice	21CFR 174 & 182 and EU 2023/2006
• Colorants	21CFR 178.3297 and Res AP(89)1
• Heavy metals	CONEG and Directive 94/62/EC
• Epoxies	(EC) No. 1895/2005

Several of these regulations require overall and specific migration testing using a food substitute. Different countries have different migration testing requirements. More detail on prioritising the applicable clauses is contained at the end of the submission. In Section 3.

All stakeholders are invited to respond to questions posed in this Consultation Paper. NCI has the following response to the questions posed.

Please indicate if you are a:

- ☐ Raw material provider
- X Packaging manufacturer/converter/provider
- ☐ Peak industry/trade association
- ☐ Food business (manufacturer/importer/brand owner/retailer)
- ☐ Consumer
- ☐ Government representative (State/territory or Commonwealth agency)
- ☐ Public health representative
- ☐ Other (please specify)
-

Around 130 people in New Zealand and around 464 in Australia.

If you are a business, please indicate the approximate number of employees in your business:

- ☐ 1 – 20
- ☐ 20 – 200
- X >200

2.1 Question 1 (refer to p. 9)

What concerns, if any, do you have about food packaging in relation to food safety?

☐None

Please expand on your response

NCI wishes to provide safe containers to the organisations using our product and respond with detailed declarations of compliance.

2.2 Question 2 (refer to p. 9)

What measures do you think could be implemented to resolve these concerns?

☐None

Please expand on your response

Better definition in New Zealand as to what a safe food contact material is. This should relate to EU and FDA regulations as these are internationally recognised and very detailed in their requirements.

2.3 Question 3 (refer to p.11)

If you are a packaging manufacturer/converter/supplier, please detail the types (s) and relative volumes for the different food packaging materials produced by your business and whether the main components are imported or made locally (in Australia or New Zealand).

Type of packaging material (for example)	Volume (ktpa*)	Local/Imported
Carton board (folding)	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Cardboard/paper (virgin)	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Cardboard/paper (recycled)	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic mono-layers	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic multi-layers	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic laminate	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic rigid NCI produces these in Australia.	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic co-extruded	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Plastic (recycled)	☐0 – 50	☐Local

	☐50 – 500 ☐500 - 5000	☐Imported
Metal NCI produces metal food packaging mainly in New Zealand	X 0 – 50 ☐50 – 500 ☐500 - 5000	X Local ☐Imported
Composites (eg. Paper/foil/plastic)	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Glass	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Ceramic	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported
Other	☐0 – 50 ☐50 – 500 ☐500 - 5000	☐Local ☐Imported

**Kilo tonnes per annum*

2.4 Question 4 (refer to p. 12)

If you are a peak body/trade association, do you have the expertise to offer food safety advice on chemical migration from packaging into food (CMPF) to businesses within the packaging supply chain?

☐ **No**

☐ **Yes**

Please expand on your response

We are not a trade organisation but do have a significant understanding of the food safety regulations

2.5 Question 5 (refer to p. 12)

As a peak body/trade association, is there a need for access to further advice on CMPF?

☐ No

☐ Yes

Please expand on your response

2.6 Question 6 (refer to p.13)

Can you please identify the risk identification, characterisation and mitigation strategies that your business uses and whether you use any others?

Please indicate which responses apply

X Adherence to either a mandatory or voluntary standard, Code of Practice (CoP), handbook or guideline that provides guidance on mitigation of potential risks associated with CMPF

☐ Prohibition of specific chemicals that should not be present in food if it is determined that they may migrate into food and present a significant risk

☐ Prescriptive regulatory requirements for CMPF to address identified risks (e.g. maximum limits, migratory limits)

X Recognition of other countries' approaches and/or requirements used to mitigate risk and adopting these for use in Australia/New Zealand.

X Use of certificates of compliance confirming that packaging and packaging inputs adhere to a specific CoP, industry standard or regulation

☐ Instructions in the form of labelling requirements to mitigate risks at the consumer level (e.g. preparation instructions).

☐ Introduction of a post-market incident response mechanism (for example, to review poor or lack of application of Good Manufacturing Practice (GMP)).

☐ Establishment by packaging and food manufacturing companies of internal specifications and due diligence systems for packaging supply/use.

☐ Other

As discussed above we use USFDA and EU regulations

2.7 Question 7 (refer to p. 14)

Is information readily available on whether or not food packaging (including for home brand products) is made from recycled materials?

☐ No

☐ Yes

Please expand on your response

2.8 Question 8 (refer to p.14)

If yes to Question 7, how do you ensure that packaging manufactured from recycled materials does not contain chemicals that could migrate into food at levels of potential concern?

☐ In-house testing

☐ Request Declaration of Compliance

☐ Auditing of supplier

☐ Other (please specify)

2.9 Question 9 (*refer to p.16*)

If you are a packaging or food manufacturer, or industry body, is using another countries' legislation (eg US/EU) suitable to ensure compliance with your customer's needs?

☐ No

☒ Yes

Please expand on your response

As above, we use USFDA, EU, China, Japan and sometimes, Indonesia, Malaysia, Taiwan. The Australian/New Zealand standard really adds nothing to our assessment using these other regulations.

2.10 Question 10 (*refer to p.16*)

In your experience, do the EU or US requirements or guidelines and other CoPs adequately manage risks from CMPF from all recycled materials?

☐ No

☐ Yes

Please expand on your response

We don't deal in recycled materials.

2.11 Question 11 (*refer to p.17*)

What would you see as the advantages and disadvantages of a co-regulatory approach to managing CMPF?

Advantages

Industry has a more practical knowledge of what can feasibly be done.

Disadvantages

Too many inputs makes it hard to get consensus.

2.12 Question 12 (*refer to p.17*)

Does the Australian Standard for Plastic Materials for Food Contact Use – AS2070-1999 supply useful guidance to industry?

X No

☐ Yes

Please expand on your response

As stated above, this standard is only for plastic whereas metal and paper are widely used. In addition there is poor definition of what is considered to be safe. Using the overseas regulations would provide more certainty although they too do not define which aspect is more important than another. NCI considers the ones listed above cover a range of attributes which if complied with should mean there is minimal concern over the safety of food.

2.13 Question 13 (refer to p.17)

Are there other pertinent industry standards (Australian/New Zealand or International) that you reference and adhere to regularly?

☐ No

X Yes

Please expand on your response

As discussed above

2.14 Question 14 (*refer to p.18*)

Would you see benefits if a more prescriptive approach to packaging regulations were introduced?

☐ No

X Yes

Please expand on your response

As long as the prescriptive regulations weren't too picky and focussed on the main attributes that should determine a product is safe. For example there are EU regulations on encephalopathy risk from the use of animal products in coatings, as well as regulations on food based allergens. Neither of these are relevant to coatings. Also dual use substances are not overly of concern.

2.15 Question 15 (refer to p.18)

Regardless of whether you buy or manufacture packaging, do you have a food safety or quality management program for that packaging?

☐ No

☒ Yes

Please expand on your response

We are ISO9001 accredited and have a HACCP programme. We are also implementing FSSC22000

2.16 Question 16 (refer to p.18)

What are the key elements pertaining to chemical migration from packaging of this program (if you have one)?

For example, do you comply with a code of practice(s) or a specialist customised in-house program.

☒ Comply with requirements in Australia New Zealand Food Standards Code

☒ Comply with AS 2070-1999

☒ Comply with Good Manufacturing Practice

☒ Comply with EU regulations

☒ Comply with US regulations

☐ Comply with CoP (if so, which?)

☐ Comply with customised in-house program

☐ Ensure through chain product stewardship

☐ Other

2.17 Question 17 (refer to p.18)

As a food business, what quality assurance and quality controls do you currently use to mitigate risks from CMPF? Please provide examples.

Quality Assurance

Coating quality tests, HACCP, biological surveys

Quality Controls

hairnets and sanitising etc. Implementing ISO and FSSC programmes.

2.18 Question 18 (*refer to p.18*)

As a food business, do you have in-house technical capacity or expertise related to packaging?

☐ No

☒ Yes

Please expand on your response

Full time plant chemist/compliance manager, technical engineer, quality manager, H&S and food programme manager.

2.19 Question 19 (refer to p.18)

As a packaging manufacturer/converter/supplier (including packaging importer), if you print on the materials that you produce, do you have a quality assurance and quality control system (or similar) which includes printing inks and related products (eg. resins, adjuvants, mineral oil) ?

☐ No

☒ Yes

Please expand on your response

We have instituted process controls to manage ink offset and only use food compliant inks.

2.20 Question 20 (refer to p.18)

As a packaging manufacturer/converter/supplier (including packaging importer), do your quality assurance/quality control systems consider the end uses of the packaging ?

☐ No

☒ Yes

Please expand on your response

Milk powder cans have different requirements to seafood or meat products. The quality testing includes checks for specific coating types.

2.21 Question 21 (refer to p.18)

As a packaging manufacturer/converter/supplier (including packaging importer), do you always prepare a Declaration of Compliance with existing legislation in order to meet your customers' needs?

☐ No

☒ Yes

Please expand on your response

When requested by customers we prepare declarations.

2.22 Question 22 (refer to p.18 and SD3)

As a packaging manufacturer/converter/supplier (including packaging importer), as a result of international responses to issues with CMPF (eg. di-2-ethylhexyl adipate (DEHA)), and management measures undertaken by overseas manufacturers (eg. reformulation), have you adopted similar mitigation measures?

☐ No

☒ Yes

Please expand on your response

We are investigating options of BPA free coatings with suppliers and make requests for statements on US and EU food safety requirements.

2.23 Question 23 (refer to p.18 and SD3)

As a packaging manufacturer/converter/supplier (including packaging importer), are you aware if semicarbazide is still used in manufacturing of food packaging materials in Australia and/or New Zealand?

X No

☐ Yes

Please expand on your response

On review of SDS sheets provided by coating manufacturers, it is possible that it is present in the sealing compound/gasket of imported glass closures.

Please detail any other comments you have on the Consultation Paper and the issues raised:

See below

3 Analysis of FDA and EU Regulations

The most applicable parts of the EU and FDA regulations are presented in the following table as an expansion of the categories summarised at the start of this submission.

Requirements	Topic	Importance, (H)igh, (M)edium, (L)ow	Comment
US FDA			
21CFR 170	General Requirements	H	This section in conjunction with (EC) No. 1935/2004 and AS2070:1999 4.1.1 all require that the coating is safe and the organoleptic qualities of the packaging is safe. This is a basic requirement that should be part of the review.
21CFR 174 & 182	Good Manufacturing Practice	H	This section does not have as much detail as (EC) No. 2023/2006 and therefore compliance with the latter clause is more relevant.
21CFR 175.300	Resinous and Polymeric Coatings	H	Acceptable ingredients of coatings are listed in this regulation and therefore the coatings need to be checked if they are appropriate. Often this clause is the only aspect of 21CFR that is reported on. I am not sure if this is the accepted norm in the US.
	End-use restrictions compliant with intended food type	H	This clause advises if any of the components of the coating are not suitable for storing specific materials or not. Common conditions are that the food should not contain more than 8% alcohol or be fat based. Some plasticisers can leach out of coatings into fatty material.
21CFR 178	Indirect food additives: Adjuvants Production aids and sanitizers	M	Besides PVC there probably aren't a lot of these materials used so compliance with this category isn't as important.
21CFR 178.3297	Colorants	H	It is important that materials used for colouring coatings do not contain any hazardous chemicals. Many of the coatings are naturally coloured gold so this section is not a big deal. White ones are typically made using titanium dioxide which also is inert. Most commonly the EU clause CoE Resolution AP(89)1 is reported on. AS2070:1999 4.1.2 also requires comment on colorants as per AP(89)1.
21CFR 181.27	Plasticisers	M	Some plasticisers are allowed as additives. As stated above, plasticisers are used more in PVC materials. This clause is not as important.
21CFR 189 subpart B	Prohibited animal material	L	This section as well as Commission Decision No. 2001/2/EC Amending Decision 2000/418/EC discuss the use of animal products from sick animals etc. Animal products are not typically used in coating formulations and the stoving process would kill off any biological material so there is limited risk with the use of animal

Requirements	Topic	Importance, (H)igh, (M)edium, (L)ow	Comment
			products and therefore there is not much need to report on this aspect. Depending on the country of export, halal and other cultural considerations can be important.
21CFR 189 subparts C & D	Prohibited materials	H	This clause lists a small number of chemicals that are prohibited. Manufacturers are unlikely to use these and therefore reporting on this clause is not necessary.
21CFR 109.15 or 30	Poly Chlorinated Biphenyls	H	PCBs are not particularly prevalent in the environment now and therefore reporting on this both in this clause and in the ANZ Food Standards Code - Standard 1.4.1 (2)(2) and (3)(2) is not necessary.
(CONEG)	Heavy metals	H	It is important to know whether the coating has lead, cadmium, mercury or chromium (VI) contained in it. This clause has the same criteria as Directive 94/62/EC
European Union (EU)			
(EC) No. 1935/2004	Overall compliance Framework	H	Important as discussed above.
RESAP(2004)1	Guidance and Specific Migration Limits	M	Testing of migration of coatings is very expensive so is not necessarily done for all coatings.
CEPE for food contact coatings	Coating Code of Practice	M	This is a voluntary code of practice that is helpful in that is lists some additional criteria over RESAP(2004)1 and offers some explanation of that regulation.
(EC) No. 2023/2006	Good Manufacturing Practice	H	Important as discussed above.
(EU) No. 10/2011 repealing Directive 2002/72/EC	Specific migration Limits for plastic food contact	M	This regulation is based on the requirements for chemical migration from plastics but has been applied to coatings on metal as well in a similar fashion that the New Zealand Standard does. Therefore strictly speaking this regulation does not apply to coatings on metal.
CoE Resolution AP(89)1	Colorants	H	Important as discussed above.
(EC) No. 1895/2005	Epoxy coatings	H	There is a lot of interest in bisphenol A (BPA) and diglycidyl ethers however both EU and FDA have advised that BPA is not overly toxic. It is however important to check the status of the coating against these requirements.
(EC) No. 1907/2006	REACH Chemicals of concern SVHC	M	There are around 155 substances that are considered to be substances of very high concern and therefore it is preferable to know whether these are in the coating or not.

Requirements	Topic	Importance, (H)igh, (M)edium, (L)ow	Comment
Directive 94/62/EC	Heavy metals	H	Important as discussed above.
Other European Union			
Commission Decision No. 2001/2/EC Amending Decision 2000/418/EC	Animal Products (Encephalopathy)	M	Not particularly important as discussed above.
New Zealand Australia			
AS2070:1999 4.1.1	General compliance with FDA or EU	H	The reason for this submission is to define further what is meant by compliance with FDA and EU.
AS2070:1999 4.1.2	Colorants used in plastic materials as per Res AP(89)1	H	Important as discussed above.
ANZ Food Standards Code - Standard 1.4.3 (2)(a) and (b)	Material contact causing harm	L	This part of the regulation is not really in line with the thrust of chemical hazards as it discusses physical hazards. This provision should be moved.
ANZ Food Standards Code - Standard 1.4.1 (2)(2) and (3)(2)	Maximum levels of contaminants in food	H	As discussed at the start of the submission, the migration limits set require costly testing of the food to show compliance. It is preferable to show there is no acrylonitrile or PVC in the coating.
Other International Regulation		L, If info available	
China			
Appendix A of GB9685-2008 including (NHFPC).	approved list of chemicals		Compliance with the Chinese regulations is proving very difficult for coating manufacturers due to every raw material and formulation needing to be included on a specific list. Currently they are up to the 4th or 5th list and still there are components of coatings that do not fit. Double seam sealing compound is similarly not included on the Chinese list.
GB4805 hygienic standard	Testing		We consider that migration testing is of more use than inclusion of the chemicals used in a coating on a list and that more weight should be applied to that, although as stated above migration testing is expensive.