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shaping the future

4 August 2016

Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6143

Dear Sir/Madam

Subject: Submission on Proposal 1034 - Chemical Migration from Packaging into Food

1 Introduction

Food Standards Australia New Zealand (FSANZ) has assessed a Proposal to develop or vary regulatory measures to control chemical migration from packaging into food. Pursuant to section 72 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

2 General Comment

NCI Packaging has been involved in the preparation of the Packaging Council of New Zealand submission and therefore supports the approach discussed in that document which is reiterated in our submission. Further regulation is not required if food safety is defined as meeting suitable existing regulations from the European Union and United States Food and Drug Administration. The proposed sections are found in the submission detail.

At a basic level we would define packaging in New Zealand as:

- Packaging manufactured inside NZ which is then filled with product in NZ. (Locally made packaging)
- Packaging manufactured outside NZ which is then filled with product in NZ. (Imported packaging)
- Packaging manufactured outside NZ which is then filled with product before being imported into NZ. (imported pre-packaged products)

NCI considers that any final framework and/or regulations determined by FSANZ to mitigate any potential risk posed by chemical migration from packaging into food (CMPF) should capture all packaging, not just locally made packaging or locally filled packaging. It needs to also capture imported fully-packaged products.

It is essential that packaging standards and enforcement are applied consistently on all packaging to ensure that domestic producers are not indirectly cross-subsidising / shielding imported goods. Without that consistent obligation 'market forces' will logically operate to increase the consumer's exposure to unregulated food at the expense of the regulated packaged food.

3 Submission Detail

Comment is made on the questions posed in the proposal document in Table 3-1.

Table 3-1 Specific Comments related to the Proposal

Q1 Do you consider that an ongoing monitoring and surveillance strategy, possibly by jurisdictions responsible for enforcement and compliance of food laws would be a practical measure to identify and manage unknown risks associated with CMPF?	In principle, we are satisfied that the ongoing regime of the Australian total diet study (ATDS) provides acceptable monitoring through agreed protocols and testing regimes. However we do have some concerns: • Testing for unknown or speculative risks can require unwarranted testing protocols and regimes. Risks which are rational are already addressed under current testing regimes. • "Food contact" is not defined. This affects both those wishing to provide assurance, and those seeking to rely on testing to provide assurance. • How is it established that the source of contamination is in fact the packaging and not the product, given the risk is a function of total exposure and contact packaging is by no means the only risk pathway. Note, migration testing is undertaken with food stimulants for this reason.
Q2 Do you agree that FSANZ's analysis of control measures and market information accurately represents how CMPF is being controlled in Australia and New Zealand? If, not please state your reasons?	It is representative, for domestically produced packaging. However, given that both jurisdictions have significant finished (pre-packaged) imports, we are not assured the same measures are being applied to products sourced from outside Australia and New Zealand.
Q3 For any industry stakeholders who have yet to respond to FSANZ's call for information: What control measures for CMPF does your business use?	NCI made an earlier submission on this issue.
Q4 What problems can you identify with the status quo option and therefore abandoning this proposal?	We support limited regulation as per our answer to Q5.
Q5 If you consider that a prescriptive approach is the most appropriate option as per either the US/and/or EU approach, FSANZ invites you to elaborate on those reasons. Specifically, please provide the pros and cons of this position in order to further identify costs and benefits for consumers, industry and government of taking a prescriptive approach?	No new regulations are required, as the USFDA and EU approaches (typically used in the larger packaging companies in New Zealand) are already prescriptive. To introduce new regulations to the Australasian market duplicates existing regulations adding unnecessary compliance and associated costs. However, we suggest that a clearly defined framework of current relevant US and EU regulations should be established, and by adopting these regulations as FSANZ regulations would provide appropriate controls for CMPF. The use of a specific set of EU and USFDA regulations would provide industry wide conformity and compliance for companies

	already using these standards and also capture those small to medium enterprises (SME) and importers who may represent an unknown risk in terms of CMPF. We have defined the applicable EU and USFDA regulations in Appendix 1
Q6 What do you see as the costs/benefits of this option for consumers, industry and government? Do you consider it would ensure industry has adequate knowledge of the risks from CMPF and implemented available risk mitigation measures?	Based on Q5. The existing standard states that packaging must be 'safe'. With no clearly defined criteria for a 'safe' product we suggest that the current regulations create two platforms (1) packaging manufacturers who are required to meet USFDA and/or EU standards for customer requirements and (2) packaging manufacturers who can simply claim their products are 'safe' without reference. Our suggestion is that 'safe' be defined in line with our answer to Q5. We see the benefits of this approach as capturing and mitigating the risks from the SME market which has been identified in the proposal documentation as the greater risk under this proposal.
Q7 Focusing on the three key areas outlined above, what information do you think would be the most suitable to include in an information/awareness program?	Based on Q5. We see no benefit in any programme which specifically educates or informs the consumer. Consumers are entitled to assume food they get is fit for purpose without having to understand the underlying science or undertake their own checks. Our suggestion under Q5 would involve a regulatory approach and therefore information and communication would be appropriate to that.
Q8 Do you agree that FSANZ, the AFGC/NZFGC and packaging peak bodies are the most appropriate organisations to undertake this program? If not, can you identify other appropriate agencies, and peak bodies?	Based on our answer to Q5. Regulators could expect to be supported by industry peak bodies.
Q9 What are the perceived cost and benefits for industry, consumers and industry of a non-regulatory approach? Do you think either option 3a, 3bor 3c would be cost effective?	Not applicable in relation to our answer in Q5.
Q10 A guideline would involve a degree of prescription (although it would not be mandated in the Code) (noting that the OBPR has advised FSANZ that it also views guidelines as a prescriptive measure). FSANZ invites stakeholders to identify the costs and benefits to industry, consumers and government of this approach in assisting industry (specifically SMEs) with identifying, characterising and managing risks arising from CMPF.	Our concern with this question is how a prescriptive approach could be achieved without being mandated? We suggest that the approach suggested in response to Q5 represents a sensible compromise, albeit an alternative to the suggested FSANZ graduated approach. There is the specific additional benefit in a limited regulation (as per our answer to Q5) if it addresses the unknown risk of food contact risk posed by SME/small importers.

Q11 Would the above information be appropriate for including in a guideline or can you identify others that should be included?	See Q7.
Q12 Should all the industry standards and CoPs identified in option 3b be included in a guideline under this current Proposal (versus a separate process) to maximise coverage of all requirements for packaging or only specific ones that include reference to food safety measures or prescribed limits in them? In your answer please be as specific as possible to identify the most-appropriate guideline that would address CMPF.	See Q8.
Q13 What do you see as costs and benefits for government, consumers and industry of this measure? Would it be cost effective? Please detail any other options that you think are appropriate, or available, to strengthen or clarify existing Code requirements and the reasons why, including the costs and benefits of such a measure?	See Q5.
Q14 Do you consider that there is scope to improve the Food Acts provisions regulating the sale of food packaging in Australia and New Zealand?	This question should be more specific in order for us to provide a considered response.
Q15 Do you consider that the Code should include specific limits for DEHP and DINP for all foods similar to the limits set used for other packaging chemicals (tin, vinyl chloride and acrylonitrile). What do you see as the costs and benefits to industry, enforcement agencies and consumers of this approach?	We suggest that the approach outlined above (Q5) would adequately address these particular chemicals, and indeed any other chemicals which may become a concern due to the monitoring e.g. the ATDS, noting our comment in Q1 regarding clearly identifying the source of chemicals. We do not consider any specific chemicals need to be singling out in packaging regulation.
Q16 Which peak bodies should be involved in familiarising industry with any new provisions or raising awareness of CMPF?	See Q8.
Q17 How could post-market surveillance be conducted satisfactorily? Who would undertake such surveillance?	See Q1.
Q18 How will the options listed affect you; such as the choices available to your business and current process practices, consumption choices or regulatory activities?	Our suggestion above (Q5) would not involve any additional level of compliance for those operating to EU and USFDA standards. It would however usefully provide a level of clarity which currently does not exist with respect to SME / importers.
Q 19 Are there other affected parties that have not been identified by FSANZ that you feel should be included?	Not that we are aware of.

Q 20 Are there specific costs or benefits to consumers, industry and/or government that you feel should be considered in a future Regulation Impact Statement? If you have any data or information to support your views on these questions, FSANZ would welcome the opportunity to consider it.	Our suggestion (Q5) could represent a cost to those companies who currently do not meet USFDA and/or EU standards. However consumers are entitled to assume products are safe. Those not meeting defined EU / USFDA standards may or may not be putting consumers at risk but should accept the costs of such assurance as a reasonable expectation of consumers and the community.

4 Conclusion

NCI remains to be convinced that any intervention related to packaging regulation is needed. However, to address this proposal we have taken a pragmatic approach which limits regulatory impact whilst still providing for a level of surety through the application of standards which are already considered minimum compliance by the majority of the industry.

Yours Faithfully

[redacted]

[redacted]

Plant Chemist/Compliance Manager

Appendix 1

General suitability of coating with food:

- 21CFR 170 Food Additives or
- EC 1935/2004: Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

Suitability of raw materials:

- 21CFR 175 Indirect Food Additives: Adhesives and Components of Coatings or
  21CFR 176 Indirect Food Additives: Paper and Paperboard Components or
  21CFR 177 Indirect Food Additives: Polymers or
  21CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; or
- 21CFR 181 Prior-Sanctioned Food Ingredients or
  21CFR 182 Substances Generally Recognized as Safe or
  21CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe or
  21CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe; or
- ResAP(2004)1: Council of Europe Framework Resolution RESAP(2004)1 on Coatings intended to come in contact with foodstuffs; or
- (EU)10/2011: Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Suitability of tinplate, base steel and tin:

- French DGCCRF 2004/64: The General Directorate of Competition, Consumption and Fraud Repression 2004/64 Materials in Contact with Foodstuffs; or
- EN10333:2005 Steel for packaging – Flat steel products intended for use in contact with food stuffs, for human and animal consumption – Tin coated steel (tinplate) &
  EN10334:2005 Steel for packaging – Flat steel products intended for use in contact with food stuffs, products and beverages for human and animal consumption – non coated steel (blackplate) &
  EN610 Tin and tin alloys. Ingot tin.

Suitability of aluminium:

- EN602:2004. Aluminium and aluminium alloys — Wrought products — Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuff.

Prohibited materials:

- Animal based materials 21CFR 189 Substances Prohibited from use in Human Food or
  EU Commission Decision No. 2000/418/EC regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and
- For general chemicals (EC) No. 1907/2006: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Good Manufacturing Practice:

- 21CFR 174.5(a) General provisions applicable to indirect food additives &
  21CFR 182.1(b) Substances Generally Recognized As Safe; or
- EU 2023/2006 Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Colorants:

- 21CFR 178.3297: Colorants for polymers or
- Res AP(89)1: Council of Europe Committee of Ministers, Resolution AP (89)1 on the use of Colorants in plastics materials coming into contact with food.

Verification of no intentional addition of PCBs:

- 21CFR 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials and Aus/NZ FSANZ maximum limit in food.

Heavy metals:

- CONEG: Coalition of North Eastern Governors (CONEG) Toxics in Packaging Model Legislation; or
- Directive 94/62/EC: European Parliament and Council Directive 94/62/EC on packaging and packaging waste.

Epoxies:

- (EC) No. 1895/2005: Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

Inks:

- Inks on the non food contact side of a package should comply with the Swiss Ordinance of the FDHA on Materials and Articles (817.023.21); or
- the EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles November 2011.