

**10 June 2016**  
**[14–16]**

## **Call for submissions – Proposal P1034**

### **Chemical Migration from Packaging into Food**

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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.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 5 August 2016**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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## Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingintoFood.aspx>:

SD1	Summary of state, territory and New Zealand Food Acts
SD2	<i>Australia New Zealand Food Standards Code requirements</i>
SD3	Risk profile
SD4	Analysis of control measures
SD5	Estimation of the residual risk
SD6	International regulatory approaches to chemical migration from packaging into food
SD7	Summary of submissions

# Executive summary

Food packaging is essential. It extends shelf life and prevents microbial contamination. It allows food to be transported easily and conveniently and allows information to be conveyed to consumers. However, the safety of packaging has been questioned, particularly the issue of chemical migration from packaging into food (CMPF) and the adequacy of the current regulatory framework to manage any risks resulting from that migration.

This Proposal aims to determine whether measures are required to manage food safety risks arising from CMPF in Australia and New Zealand. The Proposal encompasses CMPF from virgin and recycled materials.

FSANZ has assessed the risk of CMPF by developing a risk profile of potential chemical hazards associated with packaging chemicals and analysing control measures used throughout the packaging supply chain to mitigate CMPF. The resulting residual risk provides a qualitative assessment which indicates there are some gaps in current risk management.

The risk profile indicated that most chemicals used to produce food packaging are unlikely to pose a public health and safety concern, predominantly because of their low levels of migration into food. This conclusion is supported by information on hazard and dietary exposure for a large number of food packaging chemicals. It is also consistent with the findings of analytical surveys investigating the presence of specific packaging chemicals in Australian foods. However, FSANZ identified two chemicals for which additional food concentration data are required to determine if dietary exposure to these chemicals poses a health risk. These two chemicals, diethylhexyl phthalate (DEHP) and diisononyl phthalate (DINP), are phthalate compounds which can migrate efficiently into foods. FSANZ is now conducting a study to acquire data on DEHP and DINP levels in a wider range of foods.

Consultation with a broad range of industry stakeholders informed an analysis of the range of control measures employed to control CMPF. Overall, industry responses indicate that more general food safety control measures are used by food companies closer to the point of sale. Packaging manufacturers and raw material suppliers show good awareness and uptake of international packaging regulations whereas food manufacturers, in general, appear less aware of international regulations for packaging and indicated that they rely heavily upon supply chain assurance. The consistency of application of control measures by packaging manufacturers with a high market share provides FSANZ with confidence in the current implementation of control measures to prevent or limit CMPF.

Overall, consultations on uptake of control measures indicate good upstream control of CMPF. This advice was verified by evidence from analytical surveys which show that, with the exception of two phthalates, the estimated exposures to packaging chemicals detected in Australian and New Zealand foods and beverages were below internationally recognised safe levels and present a negligible to low risk to the Australian and New Zealand population. However, some food businesses showed poor awareness of CMPF and the application of suitable control measures. This appeared to be more evident for small to medium enterprises.

A range of risk management options are proposed. FSANZ's assessment, based on the information currently available, is that the option of a graduated approach may offer the most advantages in terms of protection of public health and safety and cost effectiveness. The graduated approach would address: chemicals with different risk profiles; concerns with clarity about current requirements as well as gaps in the awareness of CMPF. Stakeholders are encouraged to address the questions posed in the document. Responses will help inform FSANZ's next steps.

# 1 Introduction

## 1.1 The Proposal

Proposal P1027 was prepared to investigate whether additional measures are required to manage food safety risks arising from chemical migration from packaging into food (CMPF) in Australia and New Zealand.

FSANZ is investigating the use of packaging in food production and manufacture to add to the understanding of the nature and possible risks from CMPF. FSANZ is also seeking to determine whether current risk mitigation measures employed by industry are sufficient to address any risks or whether other measures might be needed.

FSANZ is considering chemicals migrating from packaging materials into food offered for retail sale (including food sold for catering purposes) and chemicals that could migrate to food indirectly e.g. during the food manufacturing process. Subsequent work will explore new technologies i.e. active and intelligent packaging; modified atmosphere packaging; and nanomaterials.

There is significant global trade in packaged food products and Australia/New Zealand are part of this market. The value of food packaging is far-reaching. It enables food to be transported, prevents microbial contamination, increases shelf life and conveys information whilst providing convenience for consumers. However there are many chemicals involved in the manufacture of packaging and some have potential to migrate into food<sup>1</sup>. There is also increased demand for the use of recycled packaging materials and potential for chemical migration from unknown complex mixtures of recycled and re-used packaging materials.

Chemical migration is influenced not only by the composition of the packaging material, but other factors including: the nature of food, the method of preservation, the ambient oxygen, moisture, light, temperature and shelf life of the food (Cirillo et al.; 2013; Muncke, 2014; Robertson, 2013). All these factors affect whether chemicals migrate into food from packaging.

This Proposal has prompted an appraisal of requirements relating to food packaging in the *Australia New Zealand Food Standards Code* (the Code). The Code includes:

- outcomes-based standards that have general requirements for packaging materials to be fit for their intended use and not contaminate food
- specific requirements that regulate the use of three particular packaging-related contaminants, for example in Standard 1.4.1.

In contrast, the United States of America (USA) and member countries of the European Union (EU) have more specific and prescriptive requirements to control CMPF. These benchmark regulations are recognised globally and most other countries either adopt them or use them as the foundation for their own regulations<sup>2</sup>.

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<sup>1</sup> See FSANZ's first consultation paper for a description of how chemical migration from packaging into food may occur: <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-Consult-CFS.docx>

<sup>2</sup> See Consultation Paper SD2 – International regulations for food contact materials: <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-CFS-SD2.pdf>

Despite industry's uptake of a range of international regulatory and non-regulatory risk mitigation measures (e.g. quality assurance and supplier assurance measures), there have been several international responses (including recalls) relating to CMPF<sup>3</sup>. Some of these incidents arose because of new evaluations of contaminants by regulatory agencies and/or some permission for packaging materials no longer being in use in packaging in the EU or USA. Some of these incidents have been traced back to inadequate quality assurance or control practices in the packaging supply chain. In these instances some industry members responded by reformulating and phasing-out certain materials. However, consultations with stakeholders indicate that in Australia and New Zealand there are some gaps in the awareness and management of CMPF and control practices are applied inconsistently.

The evidence base for this work includes analytical surveys on packaging chemicals<sup>4</sup> which have shown low levels of migration of most packaging chemicals in Australian and New Zealand foods. Most chemicals tested for were not detected at all but there is evidence that two packaging chemicals (certain phthalates) may be present in food at levels above EU compliance limits. FSANZ is conducting a study to determine if dietary exposure to these phthalates poses a health risk. For some other chemicals detected FSANZ is not aware of any regulations (in the USA, EU or elsewhere) as health-based guidance values (HBGV) have not been set. However, based on the low levels of detection, the risk was assessed to be negligible.

Currently, the safety of the food supply with respect to the risk from CMPF depends on industry in Australia and New Zealand being aware of, and voluntarily complying with, US and/or EU regulations and/or other packaging codes of practice (CoP), guidelines or self-imposed safety requirements consistent with Food Act requirements. Some businesses may also rely on the compliance of upstream packaging and food manufacturers. In consultation with FSANZ, stakeholders have shown support for further development of non-regulatory and/or regulatory measures for managing food safety risks associated with CMPF from food packaging. Such measures could provide certainty for industry on how to manage the potential public health risks arising from CMPF and consumer confidence that adequate protection is in place in Australia and New Zealand.

A holistic approach has been taken to develop a picture of the residual risk from CMPF. Three main streams of work were undertaken: a risk profile of chemicals used in the production of food packaging; analysis of control measures used by industry and consideration of risk management options, including regulatory and non-regulatory approaches.

## 1.2 The current regulatory framework

Legislative requirements in Australia and New Zealand, including state and territory Food Acts, require food to be safe and suitable. State and territory Food Acts and the New Zealand *Food Act 2014* contain general provisions for packaging that make it an offence to sell food packaging or handling materials that are unsafe or will make food unsafe, and food businesses must comply with requirements in the Code (refer to Supporting Document (SD) 1).

This means that at present, food safety risks from CMPF are managed primarily through Food Act requirements binding on those who sell food packaging and food businesses that package food for sale. To ensure that they meet requirements, food packaging manufacturers in Australia and New Zealand voluntarily apply standards imposed under overseas laws (and which do not apply in Australia or New Zealand) and/or under packaging codes of practice or guidelines.

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<sup>3</sup> See FSANZ's Consultation Paper SD 3 - International responses to chemical migration from packaging into food: <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-CFS-SD3.pdf>

<sup>4</sup> See FSANZ website <http://www.foodstandards.gov.au/Pages/default.aspx>

### **1.2.1 The Code provisions**

Relevant requirements in the Code pertinent to both Australia and New Zealand include general packaging requirements in Standard 1.1.1 (subsections 1.1.1—10(10) and (11) (*Packaging requirements*) and maximum levels (MLs) for three packaging contaminants, regulated by subsection 1.1.1—10(5) and Standard 1.4.1 – Contaminants and natural toxicants. Details of maximum levels for specific foods are provided in Schedule 19 (sections S19—4 (metal contaminants) and S19—5 (non-metal contaminants)<sup>5</sup>. Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks has requirements for chemical limits in packaged water which align with World Health Organization drinking water guidelines (WHO, 2011).

For Australia, Standard 3.2.2 – Food Safety Practices and General Requirements and Standard 4.2.1 – Primary Production and Processing Standard for Seafood have requirements pertaining to food packaging. Standard 3.2.2 contains requirements for food businesses (including manufacturers, importers and retailers) regarding the safety of packaging. Standard 4.2.1 also contains requirements for seafood businesses regarding the safety of packaging (see SD2).

## **1.3 Reasons for preparing the Proposal**

The Proposal was prepared to determine whether there are any public health and safety concerns from the migration of chemicals from virgin and recycled packaging into food and whether additional measures are required to manage this. This work provides the food regulatory system and all stakeholders with the opportunity to consider FSANZ's review of current practices and further investigate any gaps which may be addressed through regulatory or non-regulatory risk management options. This Proposal also aims to find a pathway to address CMPF issues as they emerge and to provide a framework for how these might be managed in the future.

## **1.4 Procedure for assessment**

The Proposal is being assessed under the Major Procedure (which means it includes at least two rounds of public consultation).

# **2 Summary of the assessment**

## **2.1 Summary of issues raised in submissions**

FSANZ released a consultation paper on CMPF for public comment in November 2014<sup>6</sup>. The paper presented an overview of the packaging supply chain, potential public health issues associated with CMPF, and the range of control measures which address chemical migration. Questions were posed to gather information on the size and range of the food packaging market, the packaging type that is used and the standards and practices packaging manufacturers and food manufacturers are using to manage any risks relating to this issue.

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<sup>5</sup> Regardless of whether or not an ML exists in the Code, the levels of contaminants in all foods should be kept As *Low As Reasonably Achievable* (the ALARA principle).

<sup>6</sup> The Consultation Paper, supporting documents and submissions received are available on the FSANZ website: <http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingintoFood.aspx>

The consultation paper generated a high level of interest and was well received as evidenced by the number and quality of submissions. Thirty-seven submissions were received from a broad range of Trans-Tasman stakeholders including, industry, government authorities and consumers.

FSANZ has had regard to the submissions and the issues raised. These are summarised in SD7.

Submitters recommended that FSANZ take a proportionate and informed approach to introducing any risk mitigation measures. Overall there was a call for greater guidance and information for industry on CMPF, what control measures can be used and how they can meet Code requirements. Specific industry submitters (in particular large packaging manufacturers and industry peak bodies) suggested that the risk from CMPF was low and did not require a prescriptive approach or any change to the Code. They emphasised that there is sufficient identification and mitigation of risks in place through various parallel measures such as voluntary adherence to international regulations (e.g. EU/US), Codes of Practice and in-house quality assurance schemes for a range of packaging materials.

In contrast, other industry submissions as well as government, consumers and non-government organisations expressed a view that there is a potential risk from CMPF. They also suggested there are gaps in both the knowledge and awareness of regulations for CMPF, particularly for small-to-medium enterprises (SME's), and that this could be addressed by a risk-based prescriptive requirement in the Code and further education for SME's. There was a call for FSANZ to focus on recycled materials, printing inks, imported packaging and to broaden the scope of the Proposal to include all types of packaging materials. The current assessment considers virgin and recycled packaging materials (including chemicals associated with paper and paperboard, plastics, metal, glass, printing inks and adhesives), irrespective of the source of the material (domestically produced or imported). Information on imported packaging is detailed in SD4. The health and safety risks arising from food produced using modified atmosphere packaging, active and intelligent packaging and nanomaterials was excluded from the scope of Proposal P1034 as the risks associated with CMPF from these packaging materials will be the subject of a subsequent examination.

## **2.2 Risk assessment**

### **2.2.1 Risk profile**

Food packaging is manufactured from a range of materials including glass, paper/ paperboard, a variety of plastics, and metals such as aluminium and steel. The bulk packaging material is often modified due to the use of adhesives, protective coatings and printing inks, for example. Several thousand chemicals are used in the manufacture of food packaging and other materials that come into contact with food during its production and processing.

In order to gain an understanding of the risk posed by chemical migration from packaging into food, FSANZ has investigated the hazard characteristics of chemicals used in the production of food packaging, and estimated dietary exposure to these chemicals due to migration into food. Use of the threshold of toxicological concern (TTC) concept has been particularly valuable for this work.

The toxicological properties of packaging chemicals span a continuum ranging from innocuous ("non-toxic") to concerning (e.g. carcinogenic or toxic to reproduction/ development). For example, the EU plastics regulation contains specific permissions for the use of water and vegetable oils in the production of food contact materials, while the same regulation also lists over 30 substances that may be used in food contact materials but, because of their adverse toxicological profiles, must not be detectable in food.

The TTC approach is a screening tool, based on risk assessment principles, that categorises chemicals into various levels of safe expected exposure depending on chemical structure features. Estimated dietary exposure that is below the applicable TTC indicates no safety concern, while exposure above the threshold indicates that appropriate toxicity data on the chemical, or a close structural relative, is required to perform a safety assessment.

A TTC analysis, conducted on a US FDA database of over 1300 food contact substances, showed that for 86% of the substances, estimated dietary exposure is less than the lowest TTC value for non-genotoxic substances (1.5 µg/kg bw/day). For many of the chemicals with estimated dietary exposures exceeding their respective TTC thresholds, specific toxicity data were located in various databases and the published literature that support the safety of those chemicals. For some packaging chemicals, supporting toxicity data may not be publically available, or toxicity data on structurally related substances was used for safety assessment.

A conclusion of low risk resulting from the above analysis is consistent with the findings of analytical surveys investigating the presence of specific packaging chemicals in Australian foods. However, FSANZ has identified two chemicals for which additional food concentration data are required in order to determine if dietary exposure to these chemicals poses a health risk. These two chemicals, DEHP and DINP, belong to the phthalate family of compounds, some members of which migrate efficiently into foods. FSANZ is currently conducting a study to acquire data on DEHP and DINP levels in a wider range of foods.

The 24<sup>th</sup> ATDS also found three phthalates not on the EU or US lists of approved food substances. However, based on the low levels of detection the risk was assessed to be negligible (using conservative dietary modelling).

The potential risk from the migration into food of chemicals in recycled paperboard, particularly mineral oils, is not yet well characterised and research is ongoing internationally. FSANZ has recently conducted an analytical survey of mineral oils in packaging materials and packaged food purchased in Australia. The survey did not find widespread migration of mineral oils into food products or identify any specific public health and safety concerns.

If there was a new emerging risk associated with CMPF (for example, a packaging chemical not regulated in another countries' regulations being found present in food in Australia or New Zealand or an undefined intermediary chemical formed during a packaging recycling process) then this becomes an 'unknown' risk<sup>7</sup>.

A future mechanism to capture and characterise these unknown risks could be to implement an ongoing monitoring and surveillance strategy for chemicals that may arise from these potential risk areas, liaise with industry on what risk mitigation measures may be in place, and then reapply the residual risk decision tree (see Figure 1 below) to consider the most appropriate option(s) to manage these identified risks.

**Question:**

Q1 Do you consider that an ongoing monitoring and surveillance strategy, possibly by jurisdictions responsible for enforcement and compliance of food laws<sup>8</sup> would be a practical measure to identify and manage unknown risks associated with CMPF?

<sup>7</sup> An unknown risk refers to migrant chemicals for which the evidence did not allow a characterisation of the risk.

<sup>8</sup> For example, a future survey could be considered under the Implementation Subcommittee for Food Regulation's (ISFR's) Coordinated Food Survey Plan.



## 2.2.2 Analysis of control measures and market information

Analysis of control measures used by industry and market information was achieved through preliminary investigations to gain an understanding of the complex packaging supply chain, spanning from raw material inputs through to the sale of packaged food to the consumer. This information was presented in FSANZ's first consultation paper<sup>9</sup>. Supporting documents to this paper also relayed the different control measures used by industry to address CMPF, including regulatory and non-regulatory measures<sup>10</sup>.

Recycling of packaging is also an increasingly important component of the packaging supply chain as products are re-processed into new products that are then sold back into the consumer economy. Signatories to the Australian Packaging Covenant (APC)<sup>11</sup> are required to commit to developing and implementing a policy to buy products and packaging containing recycled content. Recycled packaging may be sourced domestically or from overseas and potentially may be of unknown recycled content. However APC policy requires that signatories to the covenant need to also meet safety requirements and determine if recycled content is appropriate for proposed use in food packaging<sup>12</sup>.

Consultation with a broad range of industry stakeholders<sup>13</sup> informed the analysis of the range of control measures and their uptake by different industry sectors to control CMPF (refer to SD4).

Key observations from the analysis of control measures and market information indicate that:

- In general, the closer to the point of sale in the packaging supply chain the business is, the more general the food safety control measures used. In other words, packaging businesses<sup>14</sup> show good awareness and uptake of international packaging regulations whereas food manufacturers in general, are less aware of international regulations for packaging and indicated that they mainly only refer to Australian/New Zealand food regulations. For example, more than 85% of raw material suppliers and packaging manufacturers reported that they voluntarily comply with EU and US packaging regulations (which are not binding in Australia or New Zealand) whereas only 40-50% of food manufacturers refer to these regulations.
- Raw material suppliers and packaging manufacturers also showed good uptake of non-regulatory measures such as specific packaging industry standards, Codes of Practice and adherence to Good Manufacturing Practices (GMP).
- Food manufacturers, retailers and other food businesses showed a preference for uptake of less specific non-regulatory measures (e.g. International Organization for Standardization (ISO) standards) and uptake of audited Quality Assurance/Quality Control (QA/QC) systems which may have requirements for packaging documentation.

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<sup>9</sup> See FSANZ's Consultation Paper <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-Consult-CFS.pdf> and respective SD5 – The Packaging Supply Chain.

<sup>10</sup> See FSANZ's Consultation Paper SD7 - Industry standards, Codes of Practice and guidelines: <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-CFS-SD7.pdf>

<sup>11</sup> <http://www.packagingcovenant.org.au/pages/about-apc.html>

<sup>12</sup> The APC resource, *Recycled Materials in Food Contact Applications*, contains further information on this: [http://www.packagingcovenant.org.au/data/Resources/Recycled\\_Materials\\_in\\_Food\\_Contact\\_Applications-FINAL-May-2014.pdf](http://www.packagingcovenant.org.au/data/Resources/Recycled_Materials_in_Food_Contact_Applications-FINAL-May-2014.pdf)

<sup>13</sup> Consultations were undertaken through advisory group meetings, phone interviews, surveys and responses to the Consultation Paper.

<sup>14</sup> In this context, packaging businesses include raw material suppliers; packaging manufacturers and converters.

- Through-chain stewardship is a critical factor for food businesses. Use of supplier assurance and ‘trusted’ suppliers was a recurring theme from businesses at the retail end of the supply chain.
- Some food businesses’ showed negligible or poor awareness of CMPF and the application of suitable control measures. This appeared to be more evident for small to medium enterprises (SMEs).
- Businesses would appreciate more guidance on identifying risks from CMPF and determining how they can be managed.
- Market information also points to a small number of packaging manufacturers representing a high market share<sup>15</sup>. This information, together with knowledge gained from surveys on mitigation of risks used by representatives from these businesses, shows good consistency of application of control measures which in turn provides confidence in the current implementation of control measures to prevent or limit CMPF.
- An area of unknown risk is the importation of empty packaging from countries where control measures may be poor or unknown. This could be viewed as an emerging risk as imports of empty glass, metal, paper, plastic and printing inks have all increased over the past 3 years. That said, many of the importers of empty packaging are large packaging manufacturers with good controls in place.

#### Questions:

- 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?
- 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?

### 2.2.3 The residual risk

The risk profile and control measures were taken into consideration in the overall analysis of the residual risk from CMPF. The residual risk is the remaining risk to public health posed by packaging chemicals taking into account the severity of the adverse effect, likelihood of exposure and the efficacy (including implementation) of mitigation measures. The interplay, or ‘balance’ of these the risk and control measures enables a qualitative estimation of the residual risk from CMPF (refer to SD5).

Overall the analysis of current control measures employed by raw material suppliers and packaging manufacturers in Australia and New Zealand indicates that there is good upstream control of CMPF. Furthermore, evidence from packaging surveys, including the recently published second phase of the 24<sup>th</sup> ATDS, show that the estimated exposures to packaging chemicals detected in Australian foods and beverages<sup>16</sup> were below internationally recognised safe levels and presented a negligible to low risk to the Australian and New Zealand population.

<sup>15</sup> The manufacture of paper/paperboard and plastics together represent 66% of the market share of packaging materials. Two packaging manufacturers of paper/paperboard represent 95% of the market share in Australia and three manufacturers of plastic blow moulded products represent 80% of the market share in Australia.

<sup>16</sup> This outcome has been corroborated by a similar New Zealand packaging chemical survey carried out by the Ministry of Primary Industries (B. Butow (FSANZ), 03/03 2016, pers comm.).

Therefore, on balance the residual risk from CMPF is considered low.

However as indicated by the risk profile, for two phthalates, DEHP and DINP, the screening identified a need for more comprehensive analytical data to enable a more robust assessment of any potential health and safety risks.

The pathway for deciding on the level of residual risk from a chemical hazard is illustrated in Figure 1. If there are insufficient data or uncertainty about the nature of the hazard, for example, its ability to migrate from packaging, further characterisation of the risk may be required.

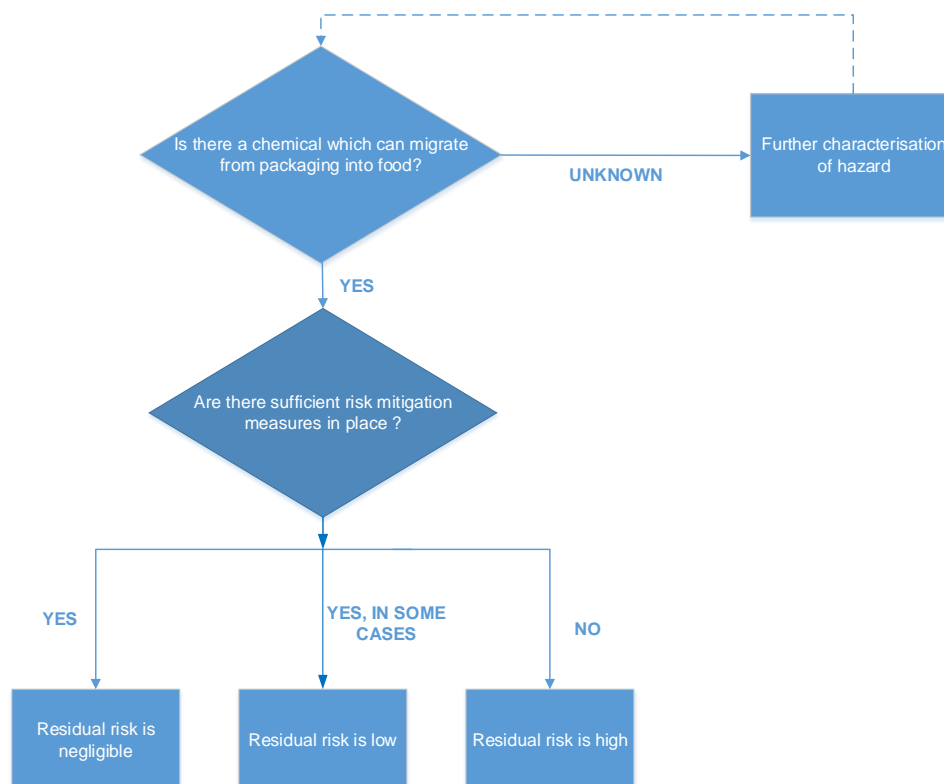


Figure 1: Residual risk decision tree

## 2.3 Risk management

This section identifies the risk management considerations taken into account in developing options to address the identified residual risk from CMPF and improve the overall management of risks compared to the current regulatory approach. We have identified the following:

- Australian and New Zealand regulations are not as prescriptive as those in many like and less developed economies
- there is lack of clarity and certainty about the current requirements (regulatory and non-regulatory) for some food businesses in Australia and New Zealand
- there are gaps in the awareness and management of CMPF for some food businesses and the application of suitable control practices are uneven across industry
- detections of two phthalates DEHP and DINP have been found from the 24<sup>th</sup> ATDS and these may have public health and safety concerns.

Taking into account FSANZ’s risk profile for CMPF (SD 3), risk management principles for setting maximum limits (MLs) in the Code and comments received in response to the consultation paper released in December 2014<sup>17</sup>, FSANZ has investigated options to improve the mitigation of CMPF (Figure 2).

Based on the information available, FSANZ’s assessment is that overall in both Australia and New Zealand there is a low risk from CMPF. However, there are specific chemicals that in FSANZ’s view pose a high risk. Having regard to these risks, and the criteria specified by section 59 of the FSANZ Act, our assessment is that there are four risk management responses available and a range of options in each.

These options are presented below (Figure 2).

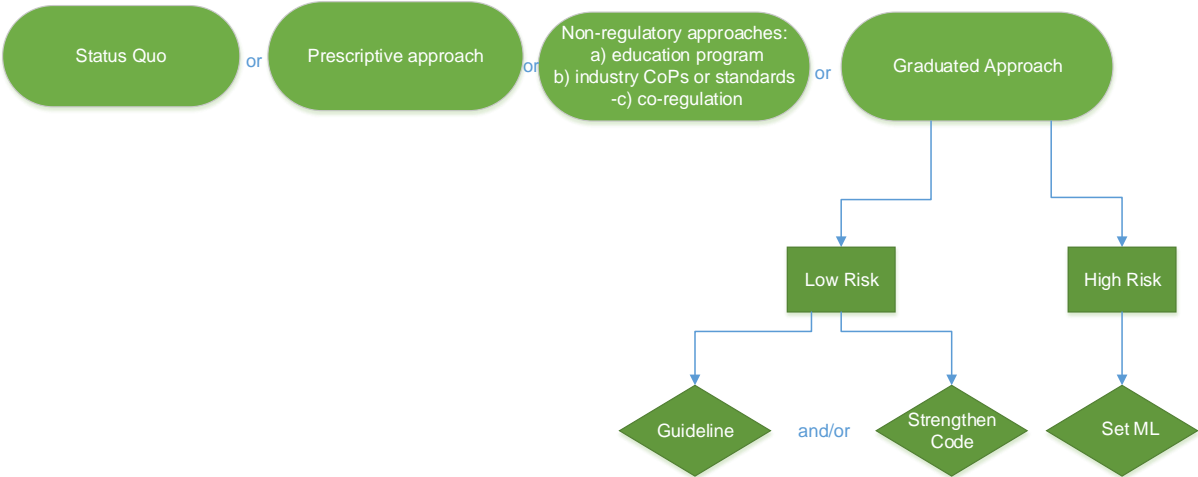


Figure 2: Risk management options.

FSANZ has presented details on these approaches to encourage discussion amongst stakeholders on potential alternatives that will improve the overall control of CMPF. FSANZ encourages stakeholders to provide submissions, detailing costs and benefits, in response to each option which will be used to inform the next stage of this Proposal.

FSANZ’s assessment based on the information currently available is that option 4 (a *graduated approach*) appears to have the most efficacy of the four options available. FSANZ has therefore presented a draft framework for discussion as a possible way of developing an alternative approach to the regulation of CMPF in Australia and New Zealand

**2.3.1 Option 1: Status quo**

In any consideration of changes to regulation, the status quo must be a part of FSANZ’s assessment. This is the base case against which other options are compared. This option would lead to an abandonment of the Proposal and continued reliance on the general provisions in the state/territory and New Zealand Food Acts (see SD 1) and on the current requirements in the Code (SD2).

As explained above, food safety risks from CMPF in Australia and New Zealand are currently managed primarily through Food Act requirements binding on those who sell food packaging and food business that package food for sale.

<sup>17</sup> Refer to Submissions to the Consultation Paper:  
<http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingintoFood.aspx>

Food packaging manufacturers in Australia and New Zealand have advised that, to ensure that they meet the Food Acts' requirements, they voluntarily apply and comply with standards imposed under overseas laws (and which do not apply in Australia or New Zealand) and/or under packaging codes of practice or guidelines.

Submissions to the consultation paper indicated that there is lack of clarity and certainty with the Code for food businesses, and gaps in the awareness and management of CMPF. The analysis of control measures indicates that control practices are uneven across industry. Therefore, it is understood that a status quo option does not address potential public health and safety issues (particularly in relation to phthalates as previously described), unknown risks and the other issues of lack of awareness and clarity in the Code.

**Question:**

Q4 What problems can you identify with the status quo option and therefore abandoning this proposal?

### **2.3.2 Option 2: Prescriptive approach**

During the course of public consultation, and submissions received in response to FSANZ's initial consultation paper<sup>18</sup>, FSANZ considered whether a purely prescriptive approach, including either a pre-market assessment or recognition of other countries regulations in the Code would be an appropriate option for Australia and New Zealand. For a comparison of international regulatory approaches to CMPF see SD6.

Some stakeholders support application of a precautionary approach to the regulation of chemicals with associated health effects. Furthermore, they claim that the 'lack of evidence of harm is not evidence of safety'. The responsibility should be on 'manufacturers to prove that food packaging is safe', rather than waiting for more definite scientific evidence that it's unsafe.

Under this option, the regulatory framework would prioritise a prescriptive approach by use of positive or negative lists which would be proportional to the risk and underpinned by a robust risk assessment.

Based on the risk profile, the current measures in the Code, state/territory and New Zealand Food Acts and control measures employed by food businesses (voluntary adoption of EU/US standards and through-chain quality control systems), the residual risk is currently low. Consequently, FSANZ assesses that a purely prescriptive approach to managing CMPF is not warranted in Australia or New Zealand.

There may be legal issues in recognising other countries' regulations in the Code as it may lead to contestability in a court to establish whether or not FSANZ had been able to satisfy itself that the best available scientific evidence was used in establishing standards in other countries, particularly if all the risk assessments were not available. In addition, the EU and US regulations do not cover all packaging materials.

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<sup>18</sup><http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingintoFood.aspx>

**Question:**

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?

**2.3.3 Option 3: Non-regulatory approaches**

This option envisages using non-regulatory approaches either by education (via information/awareness programs) (option 3a); and/or industry self-regulation by the available industry standards or codes of practice (option 3b) and/or industry self-regulation by a co-regulatory approach (Option 3c).

These non-regulatory options do not specifically address how potential unknown risks from CMPF would be managed. Reliance upon industry monitoring, evaluation and self-reporting would be needed.

***Option 3a: Education/Awareness/Information programs***

Most businesses surveyed show some level of awareness of CMPF and have (as a minimum) basic control measures in place (e.g. HACCP). Overall there is reliance by food businesses on through-chain stewardship and trusted suppliers.

However, FSANZ has identified a lack of awareness from some food manufacturer's businesses of risks of CMPF. Raising awareness with both packaging manufacturers and importers of packaging and food manufacturers to consider the safety of CMPF is a positive and practical measure.

Therefore, an information/awareness program facilitated by FSANZ, the AFGC/NZFGC and the packaging peak bodies (NZ Packaging Council and the Packaging Council of Australia) may serve to address specific gaps in both the knowledge and awareness of CMPF. An example of an information/awareness program on food packaging targeted at SMEs has been developed by the Food Standards Agency of Ireland<sup>19</sup>.

FSANZ understands from its consultations that any information/awareness program could be targeted at three key areas:

- general information for consumers
- the obligations on food businesses (particularly SMEs) to use safe packaging materials
- how a business meets those obligations in the state, territory and New Zealand food regulations and current standards in the Code to ensure the safety of packaging materials.

**Questions:**

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?

<sup>19</sup> [https://www.fsai.ie/food\\_businesses/food\\_safety\\_training/online.html](https://www.fsai.ie/food_businesses/food_safety_training/online.html) and <https://www.fsai.ie/training/fcm/story.html>

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|----|---|
| 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?  |
| 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? |

### ***Option 3b: Industry self-regulation by industry standards or codes of practice***

This option is characterised by industry formulating rules and codes of practice (CoPs), either existing or new, with industry solely responsible for their enforcement. FSANZ raised this as one possible option as no major public health and safety concerns have been associated with the majority of packaging chemicals. Furthermore, it may provide an incentive for individuals and companies to develop and comply with self-regulatory arrangements in order to mitigate hazards from CMPF.

FSANZ's consultation process identified that a range of industry standards or CoPs<sup>20</sup> are used by businesses in Australia and New Zealand, including:

- The Australian Standard – Plastics materials for food contact use (AS 2070-1999). This industry standard applies to the manufacture of plastic materials (resins, granules and powders) and colourants for food contact use and describes procedures to be followed during the various stages of processing by manufacturers of plastics items for food contact, including re-worked materials. It also references EU and US regulations.
- A range of other industry standards which have general specifications for food packaging e.g. ISO 22000; SQF 22000 and BRC standards.
- Proprietary guidance, audited quality assurance and food safety programs used by food businesses to meet supplier requirements.
- Section 6 of the AFGC's Packaging specific Product Information Form (PIF v5) refers to whether the unit packaging meets specifications for migration of substances into food<sup>21</sup>.
- NZ Packaging Council Code of Practice for Packaging Design, Education and Procurement<sup>22</sup> has no specific reference to food safety requirements, other than a general requirement to minimise risks associated with potentially toxic and hazardous materials.
- The Australian Packaging Covenant APC<sup>23</sup> has no specific reference to food safety requirements although there is a useful APC resource on 'Recycled Materials in Food Contact Applications'<sup>24</sup>
- The Confederation of European Paper Industries (CEPI) designed to provide guidance for establishing compliance with Regulation (EC) No 1935/2004. This guideline reflects the existing Recommendation XXXVI (plus parts 1, 2 and 3) of the German food safety agency (Bundesinstitut für Risikobewertung) which sets compositional limits for chemical migrants.

<sup>20</sup> <http://www.foodstandards.gov.au/code/proposals/Documents/P1034-Packaging-CFS-SD7.pdf>

<sup>21</sup> <http://www.afgc.org.au/publications/product-identification-form-pif/> (see section 6.6.2)

<sup>22</sup> <http://www.packaging.org.nz/index.php/sustainability/code-of-practice/>

<sup>23</sup> <http://www.packagingcovenant.org.au/>

<sup>24</sup> [http://www.packagingcovenant.org.au/data/Resources/Recycled\\_Materials\\_in\\_Food\\_Contact\\_Applications-FINAL-May-2014.pdf](http://www.packagingcovenant.org.au/data/Resources/Recycled_Materials_in_Food_Contact_Applications-FINAL-May-2014.pdf)

- The European Printing Ink Association (EuPIA) This guideline describes the responsibilities of printing ink manufacturers within the food packaging chain. As printing inks for food packaging are not covered by any specific EU legislation currently, EuPIA members commit that they will follow the EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles.
- Publicly Available Specification (PAS) 223: Managing Food Safety for Packaging (PAS 223).

In order for a guideline to achieve an outcome to mitigate any risks from CMPF, there needs to be readily available information about strategies to identify, characterise and manage identified risks.

### **Option 3c: Industry self-regulation by a co-regulatory approach**

Submitters to the Consultation Paper informed FSANZ that an industry/FSANZ Co-regulatory approach may have the advantage of presenting a voluntary mechanism for adoption by businesses that wish to use it, while maintaining maximum flexibility for companies to develop their own systems and approaches should they have the expertise and need to do so.

The NZ Packaging Council's Code of Practice for Packaging Design, Education and Procurement assists stakeholders in the design, manufacture and end-of-life management of packaging to minimise its environmental impacts. This CoP has recently been amended to address the New Zealand's Fair Trading Act's new prohibition against unsubstantiated representations in trade<sup>25</sup>.

The Australian Packaging Covenant (APC) was developed by industry in association with community groups and local, state and territory governments, who undertake compliance activities. It aims to change the culture of business to design more sustainable packaging, increase recycling rates and reduce packaging litter. The APC is an agreement between government, industry and community groups together to find and to fund solutions to address packaging sustainability issues. The Covenant is based on the waste hierarchy: that is, it puts high priority on avoiding and minimising packaging waste, followed by reuse, recycling, recovery and finally, disposal. More than 250 food and beverage retailers and packaging manufacturers are signatories to the APC. There are currently no requirements in the Covenant addressing CMPF.

The CoPs would take a 'due diligence' approach – 'follow this CoP and you will meet the regulatory requirements'. However, from a consumer's perspective, given the importance of protecting human health, clear standards may be preferred i.e. a more prescriptive approach.

Therefore, revising either the NZ Packaging Council Code of Practice for Packaging Design, Education and Procurement or the APC to include information on the safety of CMPF may be an appropriate and effective action that FSANZ and industry could undertake to help identify, characterise and manage risks arising from CMPF.

#### **Question:**

Q9 What are the perceived cost and benefits for industry, consumers and industry of a non-regulatory approach? Do you think either option 3a, 3b or 3c would be cost effective?

<sup>25</sup> Businesses must declare any identified safety issues with food packaging. A breach of the relevant provisions (which are set out in sections 12 A to 12 D of the *Fair Trading Act 1986* (NZ)) is a criminal offence and can result in a fine on conviction of up to \$600,000 for a company or up to \$200,000 for an individual



### 2.3.4 Option 4: Graduated approach

FSANZ's assessment, based on the information currently available, is that this option would appear to have the most efficacy of the four risk management options identified. Whilst less prescriptive than the EU or US pre-market assessment approaches, it serves to address the following:

- chemicals assessed as low risk (see 2.3.4.1)
- chemicals assessed as high risk (see 2.3.4.2); specifically, the two phthalates (DEHP and DINP) from the 24<sup>th</sup> ATDS that raise public health and safety concerns<sup>26</sup>
- a lack of clarity and certainty about the current requirements (regulatory and non-regulatory) for some food businesses in Australia and New Zealand
- gaps in the awareness and management of CMPF for some food businesses and uneven control practices across industry.

FSANZ notes, that an information/awareness program (as per option 3a) could be undertaken independent of, or as part of, a graduated approach.

#### 2.3.4.1 Chemicals of low risk

Low-risk chemicals fall into the following groups:

- chemicals of low inherent and residual risk
- chemicals where there are limited detections in food surveys and no further characterisation of the risk is warranted or being undertaken by FSANZ
- chemicals which are well managed through risk mitigation measures, including:
  - evidence of compliance with AS 2070-1999, EU and/or US regulations, and/or Codes of Practice
  - inclusion and use of barrier materials
  - documented (and validated) supplier assurance.

A range of mitigation measures are used through the packaging supply chain to minimise CMPF. Overall packaging manufacturers and raw material producers have good control of CMPF through uptake of overseas regulations. The level of control is more variable for SMEs who rely upon the Code as a point of reference. More than half of the packaging manufacturers responded that they comply with a range of non-regulatory measures and more than 70% of businesses had an audited QA/QC program (SD4).

Chemicals falling within the category of low risk would be managed through use of voluntary industry guidelines or greater record keeping and audit requirements under either a guideline and/or strengthening current requirements in the Code.

#### *Guideline approach*

Submitters on the consultation paper suggested that a specific guideline could be prepared (for example in conjunction with the Implementation Subcommittee for Food Regulation (ISFR)<sup>27</sup>) that described current regulatory requirements in Australia and New Zealand in association with practical guidance on how compliance can be achieved.

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<sup>26</sup> These public health and safety concerns are chronic in nature and FSANZ is undertaking a follow up survey to characterise the risk further.

<sup>27</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc9.htm>

For example, the following information could be considered in a guideline:

- a description of the regulatory requirements relating to managing the public health risk from the migration of chemicals from packaging into food
- identifying where the responsibility lies for ensuring chemical migration risks are managed
- steps industry might take to demonstrate compliance with the regulatory requirements
- referencing overseas standards as a means of industry demonstrating that packaging used is safe and suitable
- processes for assessing the safety of unknown packaging chemicals that may not have previously been found in food in Australia or New Zealand
- agreed enforcement strategies which will be pursued by the jurisdictions.

If guidelines are introduced they will require clarity around which business has responsibility for the compliance of the safety of the materials (packaging manufacturers i.e. suppliers and/or food manufacturers, importers or retailers) used in packaging of foods.

A guideline also needs to enable flexibility for the use of different types of food contact materials that have varying levels of contact with food. For example, long-term retail food storage packaging versus quick service restaurants' products; these represent significantly different risk profiles. An example of the type of information that could be considered in a guideline is provided in the EU guidance on Regulation No 10/2011<sup>28</sup>.

#### Questions:

- Q10 A guideline would involve a degree of prescription<sup>29</sup> (*although it would not be mandated in the Code*). 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.
- Q11 Would the above information be appropriate for including in a guideline or can you identify others that should be included?
- 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.

#### *Strengthening requirements in the Code (regulatory)*

Specific submitters have suggested that the requirements in the Code do not provide businesses with adequate information or direction to ensure that they only use packaging materials that are safe.

As explained above, the FSANZ Act limits the ability to make food standards that apply to food packaging manufacturers as opposed to food businesses that use food packaging or package food for sale. This limits the ability to make a food standard that will govern the entire packaging and food supply chain (food packaging manufacturers and suppliers (including importers of food packaging) as well as food businesses (importers and suppliers of food)).

<sup>28</sup> [http://www.contactalimentaire.com/fileadmin/ImageFichier\\_Archive/contact\\_alimentaire/Fichiers\\_Documents/guide/guidance\\_reg-10-2011\\_en.pdf](http://www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/guide/guidance_reg-10-2011_en.pdf)

<sup>29</sup> The OBPR has advised FSANZ that it also views guidelines as a prescriptive measure

However, FSANZ does have the option of amending the relevant standards in the Code to require food businesses to ensure (e.g. through certification) that the food packaging that they purchase and use has been made under GMP and meets specific standards in place internationally (e.g. EU, US or other regulations).

In Australia food law relies primarily on the substantive provisions of the Food Acts – as opposed to the Code applied by those Acts – to regulate the activities of the food packaging industry<sup>30</sup>. This reflects in part that the FSANZ Act limits the ability to make food standards that apply to food packaging manufacturers as opposed to food businesses that use food packaging or package food for sale<sup>31</sup>. Therefore, consideration of a review of the Food Act provisions could also form part of the graduated approach.

#### **Questions:**

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?

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?

#### **2.3.4.2 Chemicals of concern or high risk (regulatory approach)**

These chemicals of concern meet all or one the following criteria:

- they pose a higher inherent risk (adverse effects established from animal studies) and exceed health-based guidance limits
- there are insufficient risk mitigation measures in place to control CMPF and inadequate knowledge of the risks associated with CMPF in some businesses both of which increase the residual risk
- there is a need for further monitoring, surveillance and characterisation of the risk.

From the risk profile work FSANZ has identified two chemicals (DEHP and DINP) that meet the above criteria. Further survey work is under way to help characterise the risks of DEHP and DINP.

#### **Question:**

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?

#### **2.3.5 Post-market surveillance**

Post-market surveillance may be a key issue for Options 3 and 4. This issue can be addressed in consultation with food regulatory agencies and in a further call for submissions.

<sup>30</sup> FSANZ understands that in New Zealand the Food Act does not currently cover those who manufacture packaging; the primary responsibility placed by the Act is on the food trader.

<sup>31</sup> Section 16 of the FSANZ Act lists the matters on which FSANZ can make standards.

**Questions:**

- Q16 Which peak bodies should be involved in familiarising industry with any new provisions or raising awareness of CMPF?
- Q17 How could post-market surveillance be conducted satisfactorily? Who would undertake such surveillance?

**2.3.6 Additional risk management questions**

FSANZ also invites your additional input on the following:

**Questions:**

In order to help prepare a future regulatory impact statement (RIS) (if required), please consider the following general questions:

- 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?
- Q 19 Are there other affected parties that have not been identified by FSANZ that you feel should be included?
- 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.

**2.4 Risk communication**

Consultation is a key part of FSANZ's standards development process. FSANZ has prepared a communication strategy for this Proposal, which includes targeted communication with key stakeholders and preparing information for the broader community.

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are notified about the availability of reports for public comment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. The process by which FSANZ considers standard matters is open, accountable, consultative and transparent.

Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ places all related Proposal documents and submissions on the FSANZ website. All public comments received are reviewed and considered by the FSANZ Board in making its final decision.

**2.4.1 Advisory groups**

At the outset of the packaging project work, the FSANZ Industry Advisory Group (IAG) (comprising Trans-Tasman peak bodies, packaging industry members and large manufacturers/brand owners) provided valuable insight and information on the packaging supply chain.

From consultations with the IAG and other packaging industry members, FSANZ understands that some parts of industry (i.e. larger packaging manufacturers and food businesses) work in a tightly controlled environment generally seeking to comply with legislative requirements in other countries and voluntary codes of practice and guidelines. Some industry representatives have expressed concern that the current Food Standards Code requirements do not help industry to mitigate risks from the increased demand for use of recycled materials and the potential for chemical migration from unknown complex matrices making up these materials.

A broader advisory group, the Packaging Advisory Group (PAG) was subsequently established to advise on Proposal P1034. The PAG composition is diverse with good Trans-Tasman representation of peak bodies, industry members (including SME representation), jurisdictions and a consumer representative. Four meetings of the PAG have been held since its inception in 2014. The assessment, together with the range of possible risk management options outlined above, was presented to the PAG in early 2016. Members concurred with the outcomes of the assessment, noting that not all packaging materials pose an equal risk and that the safety of recycled plastic is of particular concern and that this needs to be addressed in any proposed control measures. In the main, PAG members supported FSANZ's risk management approach, particularly for the development of guidance for packaging suppliers, environmental health officers and food businesses.

Jurisdictions (through ISFR) have also been engaged in this work. A packaging workshop was held in December 2015 to provide an update on the Proposal's progress and to seek ISFR's insight on the management of CMPF. There was also support for FSANZ's risk management approach for CMPF.

#### **2.4.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on any proposed amendments.

### **2.5 FSANZ Act assessment requirements**

In assessing this Proposal, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

#### **2.5.1 Section 59**

##### **2.5.1.1 Cost benefit analysis**

FSANZ is not yet in a position to undertake an informed cost benefit analysis. However, FSANZ's risk profile suggests that a highly prescriptive (pre-market) risk management approach similar to that in place in the US, EU and China is not warranted. A prescriptive approach may add considerable costs into the food packaging market, especially for small to medium enterprises.

The assessment has determined that for the majority of chemicals, the residual risk is low and there are sufficient measures in place – through self-regulation (e.g. voluntary adoption by industry of EU/US standards), Australian/New Zealand Food Acts, competitive pressure within the packaging industry and the Fair Trading Acts - to mitigate most risks from chemical migration from packaging. It is considered that the costs of a prescriptive approach would outweigh the benefits.

Therefore, although FSANZ's assessment based on the information available is that a graduated approach (option 4) appears to have the most merit, all four risk management approaches have been put forward along with questions designed to elicit the costs and benefits of each. FSANZ notes, that an information/awareness program (as per option 3a) could be undertaken independent of, or as part of, a graduated approach.

#### **2.5.1.2 Other measures**

FSANZ has not yet made a decision on the development of a food regulatory measure which would be most cost effective in addressing identified risks from CMPF. FSANZ seeks comments on the four risk management options to inform its decision on whether to prepare a draft variation. As previously stated, based on the information currently available, FSANZ does not believe that a pre-market assessment approach is needed in Australia or New Zealand.

#### **2.5.1.3 Any relevant New Zealand standards**

Standards 1.1.1, 1.4.1 and 2.6.2 and Schedule 19 are joint standards.

FSANZ has had regard to the New Zealand *Food Act 2014; Animal Products Act 1999; Food Hygiene Regulations 1974 and the Wine Act 2003*. Details of the management of packaging under the New Zealand Food Act are provided in SD1.

#### **2.4.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.5.2. Subsection 18(1)**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### **2.5.2.1 Protection of public health and safety**

This Proposal is intended to improve protection of public health and safety by reviewing current requirements for chemical migration from packaging and assessing whether there is a residual risk which needs to be managed through regulatory or non-regulatory means. The Proposal also intends to address emerging issues which may present a public health concern.

#### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

Not relevant.

#### **2.5.2.3 The prevention of misleading or deceptive conduct**

Not relevant.

### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ undertook a risk profile approach to assess the inherent risk from chemicals used in packaging. This information, together with evidence from survey data and consultation on current control measures, enabled a qualitative characterisation of the residual risk from CMPF. Four risk management options have been proposed in this paper and the responses to this call for submissions will inform the decision in relation to a preferred option and any preparation of a draft variation.

- **the promotion of consistency between domestic and international food standards**

There is no generic international standard on CMPF. There is a limited amount of guidance on CMPF through the standards and guidelines developed through the Codex Alimentarius Commission (Codex), which establishes international food standards and guidelines to protect public health and safety and facilitate trade in food. The Codex General Standard for Contaminants and Toxins in Food and Feed<sup>32</sup> includes maximum levels for tin, vinyl chloride and acrylonitrile. General packaging requirements are referred to in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)<sup>33</sup>.

Despite the absence of a generic international standard on CMPF, from FSANZ's extensive consultation, it was established that a number of companies (both packaging and food) in Australia and New Zealand voluntarily apply US or EU regulations to control CMPF. This is reflected in a limited number of detections of CMPF in the most recent surveys undertaken by both FSANZ and the NZMPI, other than the two phthalates (DEHP and DINP). FSANZ's view, based on the evidence currently available, is that the adoption of US or EU regulations in or by the Code is not warranted.

This Proposal has drawn on elements of these existing international regulatory systems and considered consistency with these where appropriate within the Australia New Zealand legislative environment, having regard to the available evidence and the risk analysis.

- **the desirability of an efficient and internationally competitive food industry**

This Proposal aims to protect public health and safety and also facilitate efficiency and an internationally competitive market by creating a more level playing field for the New Zealand and Australian food industry and by being better prepared for future trends and development.

- **the promotion of fair trading in food**

No relevant issues raised.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No policy guideline is available.

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<sup>32</sup> [http://www.fao.org/fileadmin/user\\_upload/agns/pdf/CXS\\_193e.pdf](http://www.fao.org/fileadmin/user_upload/agns/pdf/CXS_193e.pdf)

<sup>33</sup> <http://www.mhlw.go.jp/english/topics/importedfoods/guideline/dl/04.pdf>

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