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[24–14]

Consultation Paper – Proposal P1034

Chemical Migration from Packaging into Food

Food Standards Australia New Zealand (FSANZ) is undertaking Proposal P1034 to assess whether there are any unmanaged public health and safety risks relating to chemical migration from packaging into food (CMPF). If any issues are identified, FSANZ will determine how they can be managed through either regulatory and/or non-regulatory means.

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. A response template with all questions in this document is available at Attachment A and a writable PDF of the questions is available via the link on [documents for public comment](#).

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) 24 December 2014

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.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the Consultation Paper for Proposal P1034 are available on the FSANZ website at

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

SD1	Current requirements in the Code for the control of chemical migration from packaging into food in Australia and New Zealand
SD2	International regulations for food contact materials
SD3	International responses to chemical migration from packaging into food
SD4	Risk assessment approaches to chemical migration from packaging into food
SD5	The packaging supply chain
SD6	Summary of responses to FSANZ industry surveys
SD7	Industry standards, Codes of Practice and guidelines

1 Introduction

1.1 Overview

The benefits of food packaging are many. Packaging allows food to be transported, prevents microbial contamination and increases shelf life providing convenience for consumers.

There are many chemicals involved in the manufacture of packaging and some of these have the potential to migrate into food. Some chemicals also have the potential to lead to harmful effects. This proposal aims to increase FSANZ's understanding of how packaging is used in food production and our understanding of the nature and possible risks from chemical migration from packaging into food (CMPF). It also seeks to determine whether current risk mitigation measures are sufficient to address any risks associated with chemical migration from packaging to food or whether other measures might be needed.

What's the issue?
Concern about possible chemical migration from packaging and potential public health effects.

As with all assessments, there is considerable uncertainty in the early stages that we aim to address in this work (e.g. in respect to the risk from chemical migration and industry's quality assurance and risk mitigation practices).

Legislative requirements in Australia and New Zealand, including state and territory Food Acts, aim to keep food safe and suitable. State and territory Food Acts and the New Zealand Food Act 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 Australia New Zealand Food Standards Code (the Code) (see SD1). The Code includes requirements for several specific packaging-related contaminants that have maximum allowable levels. The intent of the Code for all other packaging-related chemicals is that the responsibility for the safety of packaging materials rests with manufacturers and retailers. Some countries (e.g. United States (US), member countries of the European Union (EU)) have more specific and mandatory requirements for CMPF and/or extensive regulations (see SD2) compared to those in Australia and New Zealand.

FSANZ sees this proposal as an investment for the future, by ensuring our approach to the regulation of food packaging is fit for purpose.

One of the questions FSANZ is seeking to address in this Proposal is whether the current regulatory regime in Australia and New Zealand provides sufficient clarity and certainty for industry to adequately manage any potential food safety risks that may arise from CMPF. FSANZ will therefore be looking at the effectiveness of current mitigation measures to manage chemical migration and subsequent health effects.

1.2 What is the aim of this Consultation Paper?

FSANZ is seeking to collect information about the size of the packaging market, what packaging is used and what practices packaging manufacturers and food manufacturers are using to manage any risks relating to CMPF. This will broaden our understanding and help identify any gaps in the current regulatory and non-regulatory approaches for CMPF.

FSANZ is seeking input from all stakeholders to broaden its understanding of risks posed by CMPF and how industry manages these risks.

Much of this information will come from industry. However, FSANZ is also seeking consumer views during its review. Comments from jurisdictions and other stakeholders are also welcome.

A response template is at Attachment A.

1.3 Preliminary investigation

FSANZ has conducted some preliminary work on this Proposal. This work was underpinned by analytical surveys on packaging chemicals¹ and regular liaison with a range of packaging and food industry stakeholders. To help facilitate this work, an Industry Advisory Group (IAG) on food packaging was established (See Section 6).

From industry consultations, we understand 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 (CoP) and guidelines.

From an international perspective, there is significant trade in packaged food products and Australia/New Zealand are part of this global market. It is important to note that despite industry's uptake of a range of regulatory and non-regulatory risk mitigation measures, there have been several international responses (including recalls and incident responses) relating to CMPF (see SD3). Some of these incidents arose because of evolving science, new evaluation of contaminants by regulatory agencies and/or some permissions for packaging materials being out-dated in the EU or US. It is also understood that some of these incidents have been traced back to inadequate quality assurance or control practices in the packaging supply chain. In many of these cases, industry also responded by reformulating and phasing-out certain products.

Some industry representatives have expressed concern that the current requirements in the Code do not help industry to mitigate risks from the increased demand for use of recycled materials² and the potential for chemical migration from unknown complex matrices making up these materials.

Initial consultation with industry indicates that some businesses, including SMEs, may not be aware of issues with CMPF

Through consultation and surveys of industry stakeholders, including IAG members, FSANZ also identified that a number of smaller, less experienced businesses (small to medium enterprises, SMEs) may not be aware of the potential risks from CMPF and may not have in place appropriate mitigation measures. Some large companies, for example those who are end users in the packaging chain, may similarly be unaware of potential CMPF migration issues and related requirements on packaging safety.

1.4 Key findings from FSANZ's preliminary review

The preliminary work undertaken by FSANZ on CMPF investigated what evidence was available on the migration of chemicals into food from packaging materials together with the extent of industries' uptake of regulatory and non-regulatory requirements to manage food safety.

Following this preliminary work FSANZ concluded that:

- the unintended leaching of some chemicals from packaging may pose a risk to public health but there is a high degree of uncertainty about the true nature of the problem

¹ See FSANZ website <http://www.foodstandards.gov.au/Pages/default.aspx>

² The Australian Packaging Covenant defines a "Recycled material" as a material that has been reprocessed from recovered (reclaimed) material by a manufacturing process and made into a final product or into a component for a product (AS/NZS ISO 14021: 2000, Environmental labels and declarations–Self-declared environmental claims).

- the safety of the food supply with respect to this risk depends on industry in Australia and New Zealand being aware of, and complying with, US and/or EU regulations and/or other packaging Codes of Practice, guidelines or self-imposed safety requirements consistent with Food Act requirements
- for some packaging materials and chemicals, or combinations of chemicals, there may be risks that are not defined e.g. risks associated with recycled packaging, additive effects of chemicals
- mandatory regulatory requirements in Standard 1.4.3 of the Code are not as extensive as regulatory requirements for food packaging materials in countries with comparable food regulatory frameworks (e.g. US, EU, Canada)
- FSANZ's analytical surveys have shown low levels of some packaging chemicals in Australian foods (most chemicals tested for were not detected at all but there is evidence from some overseas surveys that some packaging chemicals may be present in food at levels above EU compliance limits)
- for some of the chemicals detected, there may not be any regulations (in the USA, EU or elsewhere) as health-based guidance values (HBGV) have not been set.

From stakeholder consultations and advice from IAG members, there was support for further development of non-regulatory and regulatory measures for managing food safety risks associated with food packaging materials used for food sold in Australia and New Zealand. The implementation of specific and comprehensive measures could provide certainty for industry and confidence for consumers on how to manage the potential public health risks arising from CMPF.

Through FSANZ's surveys of the IAG and other members of the food packaging industry, the key concerns raised by industry were:

- the current standard is inadequate for assisting industry to mitigate risks
- there are safety concerns around unknown, new and/or some imported packaging materials which cannot be verified as safe
- there is increasing use of recycled materials and the potential for chemical migration from unknown complex matrices.

This preliminary work allowed FSANZ to set the scope and focus for Proposal P1034.

1.5 Scope

The Proposal will consider chemicals migrating from packaging materials into food offered for retail sale (including food sold for catering purposes). It will include all packaging from which chemicals could migrate into food through direct contact with food, and other more indirect mechanisms (see Section 2). Therefore, the Proposal is not limited to chemical migration from packaging or articles in direct contact with food.

The scope of the Proposal also includes chemical migration from closures and lids, integral to the packaging, into foods.

FSANZ is looking at the potential risks from CMPF in both virgin and recycled packaging materials.

Recycled materials are identified for in-depth analysis as there is some evidence that different chemical migrants to those found in virgin materials (e.g. reaction intermediates or breakdown products) may be present under certain environmental/storage conditions or may result from the industrial processes that take place during recycling. If the constituent materials of recycled packaging are undefined, then the chemicals released from packaging into food could be unknown. Furthermore, recycled material may not be of the same quality or purity as the original material.

Proposal P1034 focuses on chemicals which may migrate from virgin and recycled packaging.

1.6 What is out of scope?

In this Proposal, FSANZ can only look at the effects of materials used in packaging on food safety, not packaging *per se*. Issues related to packaging safety, composition and utility or functionality are outside the remit of FSANZ's work (see Section 5) and are regulated by the Australian Competition and Consumer Commission (ACCC)³ or the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)⁴.

The health and safety risks arising from food produced using modified atmosphere packaging, intelligent packaging and nanomaterials are excluded from the scope of Proposal P1034. The risks associated with CMPF from these packaging materials are not well defined and may need to be examined separately. FSANZ will, however, continue to review the literature on emerging technologies and food packaging in relation to food safety. We acknowledge that there is great interest in the functionality of packaging (e.g. suitability for microwave use), and the need for manufacturers to have regard to this in their production processes.

The Proposal also excludes CMPF from cooking equipment, utensils, food vessels, storage containers and chemicals from materials that may come into contact with foods through food manufacturing processing (e.g. manufacturing surfaces, food grade oils used in machinery etc.). Consumer behaviour with regard to packaging (for example, knowledge on how consumers store and use/treat packaged food and how this may lead to chemicals migrating into food) is not being considered in the Proposal.

1.7 What are the objectives of the Proposal?

The overall objective of this Proposal is to determine whether additional measures are required to manage food safety risks arising from CMPF in Australia and New Zealand.

In this initial phase of the Proposal, we will analyse the risk that consumers may be exposed to in the current management framework and whether additional risk mitigation measures are likely to enhance the safety of the present regulatory regime above the status quo in a way that is likely to result in a net benefit to the whole community.

The specific objectives of this first stage of the Proposal are to:

1. identify and characterise potential public health and safety risks from CMPF and specifically from chemicals which may migrate from virgin packaging and recycled packaging into food
2. identify and characterise current risk mitigation measures used by industry

FSANZ intends to estimate the residual risk from CMPF to consumers and to see if there are gaps in current risk mitigation measures.

³ <https://www.accc.gov.au/>

⁴ <http://www.nicnas.gov.au/>

3. assess the residual risk to consumers in the context of the current management framework
4. determine whether the risk is adequately mitigated by current measures and evaluate whether there is a need to introduce further measures.

1.8 How will these objectives be achieved?

FSANZ aims to achieve these objectives in a number of ways, including:

- Establishment of a FSANZ Packaging Advisory Group (PAG) which includes representation from Australia and New Zealand. The PAG will provide information on industry, consumer and government views and practices, and is a way for FSANZ to obtain advice from a range of stakeholders on the adequacy of current requirements in controlling potential risks posed by chemicals migrating from packaging into food.
- Researching the risk from virgin packaging materials and recycled materials by analysing hazards posed by a range of chemical migrates and potential for exposure to these chemicals from food consumption.
- Undertaking a preliminary comparison of international approaches to the regulation of food packaging materials, particularly those in the EU and the US to identify the nature and extent of chemicals in packaging of food that may have hazardous properties and result in potential consumer exposure from the diet.
- Consulting directly with a range of packaging supply chain members in Australia and New Zealand to gain a broad understanding of the industry structure, compliance processes and any safety concerns they may have.
- Surveying food packaging manufacturers and the food industry more generally to establish current industry practices.
- Drawing on previously conducted analytical surveys investigating the concentrations of some packaging chemicals in foods and beverages in Australia to determine whether there are any potential health risks associated with observed migration levels and conducting further surveys as required.
- Gathering further information using a range of consultation mechanisms such as industry surveys, consultation papers, groups such as the Packaging Advisory Group and targeted discussions with specific sectors of the packaging industry.

2 How do chemicals migrate from packaging into food?

Generally, incidents where food has been contaminated by the migration of chemicals have involved packaging in direct contact with food (primary packaging). However, it is recognised that contamination may occur less frequently from secondary, tertiary and even quaternary packaging (such as corrugated carton, pallets and containers).

Some chemical components in packaging such as printing inks (e.g. photoinitiators such as benzophenone) may transfer to food contact surfaces via the 'set-off' process. This is a direct transfer from the external surface of the packaging to the food contact surface during stacking and storage of packaging. The chemicals may then migrate into food.

Transfer can also occur via evaporation and then leach into food via the gaseous phase (Johns et al 2000; Bradley et al 2013a). Furthermore, chemicals such as ink components and recycled fibres may persist in recycled packaging materials and ultimately migrate into food (Castle et al., 1997; Samonsek and Puype, 2013).

The type of packaging material used largely determines the potential for, and extent of, migration of chemicals into food. For apparently inert materials such as stainless steel, ceramic or glass, chemicals lining the inner surface and in direct contact with the food could lead to contamination and migration may still occur from closures or sealants containing plasticisers. Chemical migration is more likely to occur for materials such as plastics, elastomers, paper and board (Muncke, 2014).

2.1 What factors affect migration?

Chemical migration occurs for smaller size molecules and ions below 1000 Dalton⁵. Migration depends on the chemical composition and properties (e.g. polarity) and the functional properties of the packaging material (eg. crystallinity, permeability). The food type, especially the fat content of the food, is key in determining migration rates as many packaging chemicals are lipophilic (meaning they have a greater ability to dissolve in fats) and can therefore more readily migrate into fatty foods at higher rates and levels. Product filling conditions, storage conditions, shelf life and product: pack ratio will also affect the degree and rate of chemical migration into food (Robertson, 2013; Muncke, 2014). Damage to the food product packaging could potentially lead to greater chemical migration through changes in ambient oxygen, moisture, light and temperature (Robertson, 2013; Cirillo et al. 2013).

3 Potential public health risks

The risk of adverse health effects to consumers from any chemical present in food depends on the characteristics of the chemical and the exposure resulting from consuming foods containing the chemical. Various international bodies have looked at the risks posed by packaging chemicals migrating into food and this has resulted in the implementation of risk management measures for several thousand chemicals.

The primary evidence that chemical migration from packaging into food poses a potential public health risk comes from the extensive characterisation of a large number of packaging chemicals internationally (see SD2). A significant majority of these chemicals are not thought to pose a risk (see SD4) and FSANZ, together with other international scientists and regulators, are focussed on a small number of chemicals of interest. The risk assessment approaches are typically tiered, with increasing information required on the toxicology of the chemical as the migration level of the chemical increases (see SD4). Migration levels of packaging chemicals in food are typically too low to result in acute adverse health effects⁶. A major aim of risk management is, therefore, to protect consumers from potential adverse effects arising from repeated dietary exposure to packaging chemicals over a long period (chronic exposure).

3.1 Specific events

Recently, a number of food packaging substances have received close scrutiny internationally, on their potential to cause adverse health effects.

⁵unit of measurement expressing the molecular weight

⁶The potential migration of tin from tin-plated steel cans is a notable exception. Adverse effects in humans appear to be limited to acute gastric disturbances when levels of tin in food exceed 250 mg/kg.

The most notable example is bisphenol A (BPA), a chemical used in the production of polycarbonate plastics and coatings/resins used in some food packaging materials (e.g. protective linings of cans). BPA is by far the most well characterised packaging chemical in regard to both hazard characterisation and estimated dietary exposure, and is the subject of a growing number of epidemiology studies. Significant studies undertaken internationally by the US Food and Drug Administration (FDA) have shown that assertions about a causal link between BPA and a range of public health effects are unproven (see SD3).

Phthalates (esters of phthalic acid) are a class of compounds used predominantly as plasticisers in food packaging. Phthalates have attracted extensive scrutiny because they can exhibit efficient migration from packaging into foods and have shown adverse effects on reproduction/development in animal studies, notably in males (e.g. EFSA 2005a, Serrano et al 2014). Particular concerns have been raised for diethylhexyl phthalate (DEHP) which is subject to several regulations in the US CFR⁷, including the usage restriction for foods of high water content only when used as a plasticiser in food packaging material⁸ and in the EU regulations where the 'specific migration limit' (SML)⁹ for DEHP is 1.5 mg/kg food. DEHP has been detected in a Swiss survey at a concentration as high as 825 mg/kg food (Fankhauser-Noti et al 2006). High levels were also reported for two other phthalates in this survey: 270 mg/kg for diisononyl phthalate (DINP) and 740 mg/kg for diisodecyl phthalate (DIDP), both of which are regulated in Europe by a group SML of 32 mg/kg food. Ongoing compliance monitoring in the EU, in the form of the Rapid Alert System for Food and Feed (RASFF¹⁰), indicates that phthalates represent a substantial fraction of the food contact chemicals that fail regulations. A FSANZ survey in 2010 found no detections of phthalates in the products surveyed.

Food migration data on chemicals used in printing inks have also attracted attention. Notable examples are 4-methylbenzophenone (4-MBP) and 2-isopropyl thioxanthone (ITX) which are used as initiators for the curing of printing inks by UV radiation. In 2005, data from Italy showed the presence of ITX in liquid milk for babies packaged in printed carton (RASFF 2005). The EFSA risk assessment concluded that in view of the lack of toxicity data, an assessment of the safety of ITX could not be made (EFSA 2005b). EFSA re-evaluated ITX in 2007 following the provision of additional toxicity data by industry, and concluded that an assessment of potential health risks would require additional data on the effects of ITX after longer term administration (EFSA 2007). FSANZ is not aware of a subsequent risk assessment on ITX.

In 2009, German and Belgian authorities notified the migration of 4-MBP from packaging into certain cereal products (RASFF 2009). An EFSA evaluation based on the limited exposure data, and extrapolating from the toxicity of benzophenone, concluded that short term consumption of contaminated breakfast cereals should not pose a risk to most people. However, it was noted that the margin of exposure was low and recommended that more data on the occurrence of the substance in foods should be provided as well as appropriate toxicity data corresponding to the level of exposure to enable a full risk assessment (EFSA 2009). Other examples of packaging chemicals detected in food are provided in SD3.

⁷ Code of Federal Regulations

⁸ 21 CFR Ch. I: § 181.27 Plasticizers.

⁹ The SML is the maximum permitted amount of a given substance released from a material into food or food simulants (expressed as mg/kg food).

¹⁰ http://ec.europa.eu/food/safety/rasff/index_en.htm

3.2 Uncertainties

There is some scientific uncertainty¹¹ about the public health and safety risks arising from the large number of substances used in food packaging. Many substances used in packaging have not been fully characterised in terms of either the hazard characteristics and/or migration potential to allow characterisation of the risk. For example, there are no US or EU-wide measures in place for regulating substances used in printing inks, although some countries have specific legislation in place or under consideration (SD2).

Finally, there are knowledge gaps regarding the composition of recycled material used for food packaging. This raises potential concerns about the migration of unexpected/uncharacterised substances from packaging into food, for example from packaging that is manufactured using recycled materials which may not be adequately controlled with respect to chemical contamination, or for which the recycling process results in the formation of novel chemical species (e.g. Biedermann and Grob 2013).

CMPF presents a complex situation in terms of potential public health risks and , FSANZ will continue to compile further information and data and better characterise the potential risks through building a chemical risk profile.

A response template with all questions in this document is available at Attachment A

1. What concerns, if any, do you have about food packaging in relation to food safety?
2. What measures do you think could be implemented to resolve these concerns?

4 Overview of the packaging supply chain in Australia and New Zealand

The packaging manufacturing industry in Australia is estimated to be valued at \$12–13 billion (Packaging Council of Australia (PCA), personal communication). The Australian industry accounts for slightly more than 1% of the GDP, with approximately 30,000 people directly employed in the production of packaging in Australia. The New Zealand packaging industry is valued at approximately NZ\$2 billion. Three quarters of New Zealand's top 100 food and grocery brands are using packaging that is manufactured by New Zealand Packaging Council members.

The packaging supply chain includes a diverse range of businesses (Figure 1) including raw material providers, packaging manufacturers and suppliers, packaging converters, packaging importers and suppliers, food manufacturers, brand owners and retailers. Packaging is made explicitly for the products of the brand owners and the specifications of the packaging are set out by the brand owner. Retailers with private labels/home brands are the largest brand owners and are therefore a critical link in the packaging supply chain.

¹¹ For a discussion on scientific uncertainty see 'Risk Analysis in Food Regulation'
<http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx>

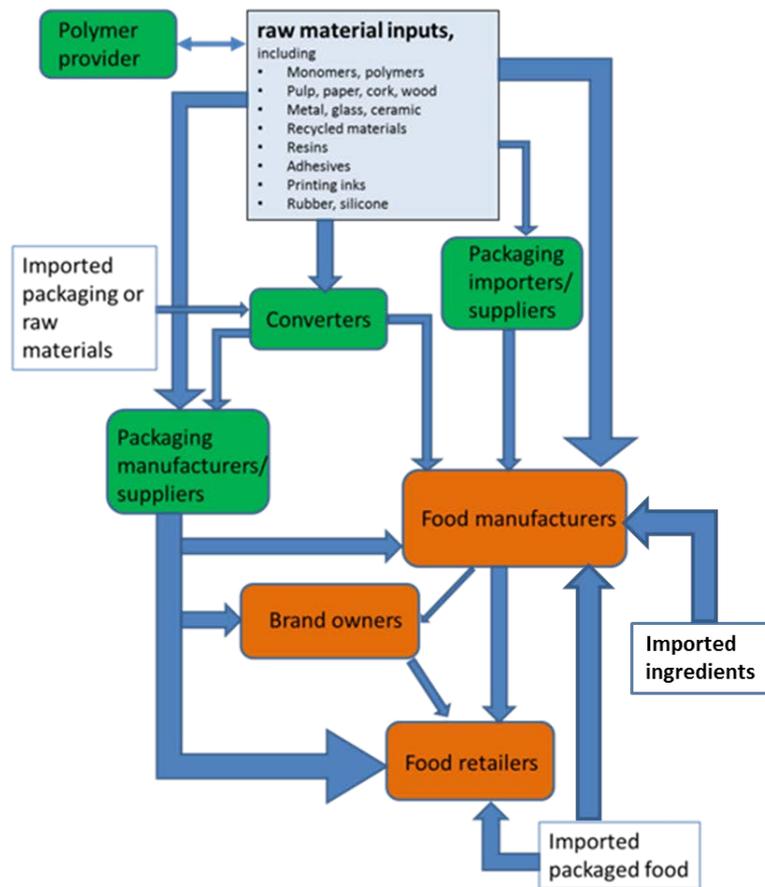


Figure 1: Overview of the packaging supply chain

Preliminary survey work carried out by FSANZ indicates that for the food industry (which includes brand owners, manufacturers and retailers), the majority of the packaging materials used are manufactured/converted in Australia and New Zealand or are from Australia and New Zealand using imported products. Approximately 19% of packaging used by the food industry is directly imported.

In Australia, the plastics packaging industry is one of the most diverse and broad in its reach across Australian society, environment and industry. Businesses range from small family-owned companies and innovative medium-sized enterprises, to leading national and multinational enterprises (Australian Plastics and Chemical Industries Association 2013). Further details on the packaging supply chain are provided at SD5.

A response template with all questions in this document is available at Attachment A

3. If you are a packaging manufacturer, please detail the type(s) and relative volumes for the different food packaging materials used in your business and whether the main component is imported or made locally (in Australia or New Zealand).

4.1 Outcomes of industry surveys

In order to consider possible implications to industry of any additional measures to manage the risk from food contact packaging materials, food packaging manufacturers and the food industry were surveyed to establish current industry practices. Two online surveys were developed to target both packaging manufacturers and the food industry. The surveys were developed with input from the IAG and were distributed through the Australian and New Zealand Food and Grocery Councils and packaging councils.

A summary table of responses, survey questions and detailed responses for both surveys are provided at SD6.

The main messages collated from survey respondents are summarised below.

- The packaging materials mostly manufactured by Australian and New Zealand manufacturers are plastic mono-layers, co-extruded plastic, rigid plastic, plastic multi-layers, cardboard/paper (virgin) carton board (folding) and glass.
- Approximately 50% of plastic-based materials are manufactured in Australia or New Zealand using imported materials.
- The majority of recycled cardboard/paper packaging is manufactured and sourced within Australia or New Zealand, whereas more than 50% of virgin cardboard/paper packaging is imported or manufactured/sourced in Australia or New Zealand using imported materials.
- Approximately half of the companies surveyed anticipate changes to the types of packaging materials used in the next five years, particularly with regards to uptake of active and intelligent packaging.
- Whilst businesses are not currently using nanotechnology in packaging, some businesses are investigating potential future uses, such as barrier improvements.
- The majority of respondents indicated that the current requirements for packaging in the Code do not suit their requirements.
- All respondents (manufacturers) refer to the EU plastics regulations and, in the majority of cases, also to the US FDA regulations.
- There was a divergence of views regarding who bears responsibility for regulatory compliance of materials used. Some respondents from the food industry took direct responsibility for packaging material compliance, whereas others stated that compliance is the responsibility of the manufacturer or raw material supplier.
- A range of general food safety systems and specific packaging Codes of Practice are employed by the food industry and packaging manufacturers.

In summary, the packaging supply chain is complex and comprises industry members both upstream (e.g. raw material producers and converters) and downstream (e.g. food manufacturers and retailers).

FSANZ consultation to date has been mainly with larger industry members of the packaging supply chain which may not be fully representative of small to medium businesses.

Consultation with some food businesses and packaging manufacturers indicated that knowledge about CMPF, and associated potential risks, is variable.

A response template with all questions in this document is available at Attachment A

4. If you are a trade association or peak body, if a risk is identified, 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?
5. Is there a need for access to further advice on CMPF?

5. Regulatory and non-regulatory control measures

As part of the consultation process and as a preliminary exercise to future assessment work, FSANZ seeks to gauge the existence and implementation of current risk management strategies for CMPF. This will help us consider any further risk management strategies that may be needed to manage any identified public health and safety risks. As FSANZ progresses the current Proposal, it is obliged to consider the potential benefits and costs that may result from any proposed control measures (non-regulatory or regulatory) for CMPF. FSANZ is required to consider all options that could achieve the desired outcome of protection of public health and safety and will examine the regulatory impacts of each option. FSANZ therefore proposes that in the future it will undertake further focussed consultation with relevant stakeholders posing questions on costings to businesses. This information will be used, along with that from other consultations with businesses (including food packaging, food manufacturing, catering etc.) to better understand the costs of the various regulatory and non-regulatory options. FSANZ may need to use the information provided to prepare a consultation Regulatory Impact Statement (RIS)¹².

On a global scale, food packaging is increasingly becoming a more competitive business with demands on both Australian and New Zealand companies to meet international best practice standards (PCA, 2005). In addition, Australia and New Zealand need to be equipped with an appropriate level of measures and strategies throughout the industry to help prevent any potential food safety risks arising from CMPF. The extent of regulatory and non-regulatory control measures and the degree of prescriptiveness of any standards aimed at mitigating the risks from CMPF will be determined by analysing the current situation in Australia and New Zealand and will be informed by responses to this paper.

5.1 Ways of mitigating risk

In order to reduce the likelihood or severity of food safety risks that may arise from CMPF, it is important to firstly understand the hazards that may be present in these materials, their potential risks and then assess a range of options that may be implemented to mitigate those risks. There may be different mitigation measures needed for different packaging materials and at different points in the production process. For example, managing the risks arising from virgin packaging materials compared to those from recycled materials could be different.

Therefore, depending on the nature of the risk, risk mitigation may consist of one or more of the following:

- adherence to either a mandatory or voluntary standard, code of practice (CoP), handbook or guideline that provides guidance on identifying, characterising and mitigating 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, migration limits)

¹² The Australian Government and the Council of Australian Governments (COAG) both require that a [Regulation Impact Statement \(RIS\)](#) be prepared for significant regulatory proposals. Regulatory Impact Statements are based on cost benefit analyses which consider and compare both the regulatory and non-regulatory options open to policy makers.

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

A response template with all questions in this document is available at Attachment A

If your business plays a role in the packaging supply chain:

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

5.2 Regulatory control measures

The current regulatory environment needs to be robust to manage any public health and safety issues potentially arising through CMPF. Although the magnitude of the risk is still uncertain, there is some evidence from recent surveys and international incidents that there may be a risk from dietary exposure to CMPF if risk mitigation strategies are not implemented comprehensively across the packaging production supply chain. Therefore, FSANZ is aiming to establish the nature and extent of risk mitigation measures in place in Australia and New Zealand to determine whether further and/or revised measures are needed to manage potential risks from CMPF.

5.2.1 The regulatory framework in Australia/New Zealand

In Australia, the state and territory Food Acts have general provisions for packaging which make it a criminal offence to sell food packaging or handling materials that are unsafe or will make the food unsafe. Food businesses must also comply with requirements in the Code.

In New Zealand, there is no approval system for packaging materials under the *Food Act 2014*, although there is a mechanism for adopting a joint food standard. The *Food Act 2014* also gives the New Zealand Ministry for Primary Industries (MPI) the ability to issue a comprehensive range of notices relating to specifications or requirements for specific matters. These include, for example, controls, restrictions, requirements and prohibitions in relation to a food sector, including how a food sector must manage or deal with risks that arise from trading in food.

Relevant requirements in the Code pertinent to Australia and New Zealand include Standard 1.4.3 – Articles in Contact with Food and Standard 1.4.1 – Contaminants and Natural Toxicants. Risks associated with the presence of a chemical contaminant in a food may be managed by establishing a maximum level (ML) for the substance. As defined in Standard 1.4.1, an ML is the maximum level of a contaminant or natural toxicant which is permitted to be present in a nominated food, typically expressed in milligrams per kilogram of food (mg/kg). An ML is established only when it serves an effective risk management function.

When established, MLs for contaminants are set at levels which are reasonably achievable from sound production and natural resource management practices. 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).

For Australia, Standard 2.6.2 also has requirements for chemical limits in packaged water which align with World Health Organization drinking water guidelines (WHO, 2011). Also for Australia, Standard 3.2.2 - Food Safety Practices and General Requirements, contains requirements for food businesses (including manufacturers, importers and retailers) regarding the safety of packaging (Attachment 1).

The Code currently makes no specific reference to the use of recycled materials in packaging; rather, there is a general requirement in Standard 1.4.3 that food packaging should be safe. This may be an area that needs addressing in order to better manage potential risks from CMPF through the use of recycled materials.

A response template with all questions in this document is available at Attachment A

If you are a food business (manufacturer/importer/brand owner/retailer):

7. Is information readily available on whether or not food packaging (including for home brand products) is made from recycled materials?
8. If yes, how do you ensure that packaging manufactured from recycled materials does not contain chemicals that could migrate into food at levels of potential concern?

5.2.2 Transitional arrangements for Code Revision and implications for Standard 1.4.3

FSANZ is currently reviewing the Code in order to improve its clarity and enable consistency in its application. This review is being undertaken through Proposal P1025¹³. FSANZ released a draft revision of the Code for public comment in May 2013 which changed the Code's structure and format. A subsequent draft revision of the Code and call for submissions was released in July 2014¹⁴.

In the draft revision of the Code, the requirements currently under Standard 1.4.3 have been brought under general packaging requirements relating to food items. Through P1025, FSANZ is also seeking to reduce the number of editorial notes in the Code. Editorial notes are not legally binding and should not contain substantive provisions. P1025 therefore proposes the removal of the editorial note to Standard 1.4.3 – Articles and Materials in Contact with Food which refers to the Australian Standard for Plastic Materials for Food Contact Use, AS 2070-1999.

5.2.3 Who regulates what in Australia and New Zealand?

In Australia, the regulation of chemicals in articles for food use is shared by several Australian Government regulatory agencies; FSANZ and the state/territory food authorities for the food sold in packaging; the NICNAS for the safety of the industrial chemicals used; and the ACCC for the safety of the packaging articles themselves.

¹³ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

¹⁴ The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code.

In New Zealand, chemicals in packaging are regulated by the Environmental Risk Management Authority (ERMA) and consumer products by the New Zealand Ministry of Consumer Affairs. The New Zealand MPI also undertakes dietary surveys and safety assessments and manages and enforces chemical contaminants in domestic and imported food.

5.2.4 International requirements

Internationally, systems regulating CMPF include one or more of the following: general safety requirements, mandatory/voluntary positive lists that allow the use of chemicals at particular levels in packaging or migrating to foods, pre-clearance requirements for the use of chemicals in packaging; no-objection letters and licensing and/or registration requirements regulating the use of chemicals in packaging. The physical, chemical and sanitary integrity of food packaging is covered by general safety requirements. The overall tenet of general requirements aims to prevent the transfer of substances from packaging to food that may be harmful to human health or which cause unacceptable changes in composition, taste or odour of the food in contact with the packaging.

A more rigorous and prescriptive approach to the control of chemicals that may migrate from packaging into foods is adopted by the US and EU in their legislative requirements. US and EU legislation tends to form the basis for other countries' and international legislation for CMPF. An overview of international requirements in this area is provided in SD2.

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 Feed¹⁵ 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)¹⁶.

A range of regulations and guidelines for recycled materials exist at the international level for plastics and paper and cardboard and were reviewed by the Australian Packaging Covenant (APC, see Section 5.2.5) in 2014. The review suggests that other countries (particularly the US and the EU) have seen the need to address the safety of recycled materials used in food applications by establishing processes to conduct risk assessments and enact legislation, when necessary, to ensure the management of risks to consumers that may arise from CMPF.

A response template with all questions in this document is available at Attachment A

9. 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?
10. As a packaging manufacturer or food business, in your experience do the EU or US requirements or guidelines and CoPs adequately manage risks from CMPF from all recycled materials?

¹⁵ http://www.fao.org/fileadmin/user_upload/agns/pdf/CXS_193e.pdf

¹⁶ <http://www.mhlw.go.jp/english/topics/importedfoods/guideline/dl/04.pdf>

5.2.5 Co-regulatory approach - The Australian Packaging Covenant

Co-regulation is an agreement between government, industry and community groups which can provide a more flexible way for industry to achieve compliance with best practice standards¹⁷. The Australian Packaging Covenant (APC)¹⁸ is an example of a co-regulatory approach. The APC is a sustainable packaging initiative developed collaboratively by industry, non-government organisations and local, state and federal government (environment) agencies and departments. It aims to change the culture of business to design more sustainable packaging, increase recycling rates and reduce packaging litter. The APC provides useful general guidance on the use of recycled materials in food contact applications¹⁹. However, there are no specific recommendations regarding CMPF and managing their food safety risks.

A recent guide²⁰ on the use of recycled materials in food contact applications was produced under the auspices of the APC which focused on:

- potential opportunities and barriers to the use of recycled materials in primary, secondary and tertiary packaging
- considerations and issues when using recycled materials
- standards and guidelines for recycled materials.

The APC also identified a range of issues to consider when incorporating recycled materials into food packaging. These consisted of consideration of the chemical composition of packaging materials, source of recycled material, the process of recycling, percentage of recycled product, packaging production process, filling process, type of food product, product application and use, storage conditions and knowledge of methodologies to ensure food safety for the selected packaging.

A response template with all questions in this document is available at Attachment A

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

5.3 Non-regulatory control measures

Voluntary standards are voluntary consensus documents developed by industry sectors that provide another risk management tool. A range of specific standards for packaging of food exist²¹, such as the Australian Standard for Plastic Materials for Food Contact Use - AS2070-1999 and Publically Available Specification (PAS) 223: Managing Food Safety for Packaging²² (SD7).

¹⁷ The Office of Best Practice Regulation defines Co-Regulation as follows: “.. a solution where industry develops and administers its own arrangement and government provides the underpinning legislation to enforce it. Such legislation can set out mandatory standards, but may provide for enforcement through a code overseen by the industry.”

¹⁸ http://www.cuttingredtape.gov.au/sites/default/files/documents/australian_government_guide_regulation.pdf

¹⁹ <http://www.packagingcovenant.org.au>

²⁰ http://www.packagingcovenant.org.au/data/Resources/Recycled_Materials_in_Food_Contact_Applications-FINAL-May-2014.pdf

²¹ http://www.packagingcovenant.org.au/data/Resources/Recycled_Materials_in_Food_Contact_Applications-FINAL-May-2014.pdf

²² <http://www.standards.org.au/InternationalEngagement/Pages/default.aspx>

²² Publicly Available Specification (PAS) 223: Managing Food Safety for Packaging

A response template with all questions in this document is available at Attachment A

12. Does Australian Standard for Plastic Materials for Food Contact Use - AS2070-1999 supply useful guidance to industry?
13. For food businesses, are there other pertinent voluntary industry standards or similar (Australian/New Zealand or International) that you reference and adhere to regularly?

CoPs and voluntary standards may also be used by food packaging businesses, including the Australian Standard – Plastics materials for food contact use (AS 2070-1999), the APC and the Publically Available Specification (PAS) 223: Managing Food Safety for Packaging (see SD7). From industry consultations to date, FSANZ understands that some parts of industry (i.e. larger packaging manufacturers and food businesses) observe legislative requirements in other countries and voluntary codes of practice and guidelines to ensure a tightly controlled environment. However, smaller, less experienced businesses may not necessarily be aware of these measures that are available to mitigate the risks from CMPF.

A recent survey undertaken by FSANZ shows that the manufacturing and food industry sectors can implement a range of general food safety systems which document the processes and checks required to manage all quality and food safety risks/hazards related to the use and manufacture of packaging. In addition, depending on the type of material produced, some manufacturers refer to specific international packaging codes of practice, for example: CEPI²³, EuPIA²⁴ or their own global companies' specific standards.

5.4 Understanding current industry practices

FSANZ is seeking from all members of the packaging supply chain a better understanding of current practices to mitigate risks associated with CMPF. This information will be vital to further work that will be undertaken for this Proposal. FSANZ has asked a number of questions throughout this document. These questions are summarised in a response template at Attachment A. You can use this writable PDF to make your submission.

A response template with all questions in this document is available at Attachment A

14. Would you see benefits if a more prescriptive approach to packaging regulations was introduced?
15. Regardless of whether you buy or manufacture packaging, do you have a food safety or quality management program for that packaging?
16. 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?

For consideration by food businesses:

17. What quality assurance and quality controls do you currently use to mitigate risks from CMPF?
18. Do you have in-house technical capacity or expertise related to packaging?

²³ Confederation of European Paper Industries

²⁴ European Printing Ink Association

For consideration by packaging manufacturer/converters/ suppliers (including importers of packaging)

19. 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)?
20. Do your quality assurance/quality control systems consider the end uses of the packaging?
21. Do you always prepare a Declaration of Compliance with existing legislation in order to meet your customers' needs?
22. 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?
23. Are you aware if semicarbazide is still used in manufacturing of food packaging materials in Australia and/or New Zealand?

6 Next steps

The questions posed in this paper are part of the consultation process to help FSANZ increase its understanding of the food packaging industry, what risk management option(s) are the most appropriate for industry and the wider community in relation to CMPF. FSANZ also welcomes any other information that stakeholders think would be useful to further consider this matter.

FSANZ will then consider all of the available views and evidence and based on this, identify any public health issues associated with CMPF and whether these issues need to be managed through additional measures. If it is decided that additional regulatory or non-regulatory measures are required, FSANZ will write a detailed report outlining the proposed measures that will be released to the public for comment, as part of our statutory process

In addition, FSANZ will continue to consult with stakeholders through the PAG, industry sectors (in particular SMEs), state and territories and New Zealand jurisdictions, as well as other government departments and consumers.

Thank you.

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All stakeholders are invited to respond to questions posed in this Consultation Paper.

Please indicate if you are a:

(required)

Raw material provider

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)

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

1–20

20–200

> 200

Question 1 (*refer to p.9*)

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

None

Please provide details of your concerns

Question 2 (*refer to p.9*)

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

None

Please provide details

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	Local
	50-500	Imported
	500-5000	
Cardboard/paper (virgin)	0-50	Local
	50-500	Imported
	500-5000	
Cardboard/paper (recycled)	0-50	Local
	50-500	Imported
	500-5000	
Plastic mono-layers	0-50	Local
	50-500	Imported
	500-5000	
Plastic multi-layers	0-50	Local
	50-500	Imported
	500-5000	
Plastic laminate	0-50	Local
	50-500	Imported
	500-5000	
Plastic rigid	0-50	Local
	50-500	Imported
	500-5000	
Plastic co-extruded	0-50	Local
	50-500	Imported
	500-5000	
Plastic (recycled)	0-50	Local
	50-500	Imported
	500-5000	
Metal	0-50	Local
	50-500	Imported
	500-5000	
Composites (eg. Paper/foil/plastic)	0-50	Local
	50-500	Imported
	500-5000	
Glass	0-50	Local
	50-500	Imported
	500-5000	
Ceramic	0-50	Local
	50-500	Imported
	500-5000	
Other	0-50	Local
	50-500	Imported
	500-5000	

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

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

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

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)

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

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

Question 7 (refer to p.14)

*If you are a food business (manufacturer/importer/brand owner/retailer):
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

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)

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

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

Question 11 (refer to p.17)

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

Advantages

Disadvantages

Question 12 (refer to p.17)

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

No Yes

Please expand on your response

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 Yes

Please expand on your response

Question 14 (refer to p.18)

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

No Yes

Please expand on your response

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

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

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

Quality Controls

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

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

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

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

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

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?

No Yes

Please expand on your response

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

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