

# Supporting Document 2

## Summary of issues raised during 2nd public consultation – Proposal P1034

Chemical Migration from Packaging into Food (Abandonment)

The following is a summary of issues raised by submitters to the 2nd public consultation paper and, where appropriate, FSANZ’s response to the issue. The issues are organised into sections according to the headings:

* General comments
* Code/Food Acts
* Public health and safety
* Control measures and market information
* Risk management options
* Ongoing monitoring and surveillance
* Costs and benefits

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| General comments | Raised by | FSANZ response |
| The AFGC recommends industry self-regulation, supported by education, awareness and information programs to address chemical migration from packaging into food.  Further, the AFGC recommends that:  1. the effectiveness of current food packaging in securing the safety of the food supply, protecting the environment, and helping consumers to select healthy diet choices is recognised.  2. FSANZ adheres closely to the principles of best practice regulation in progressing P1034.  3. FSANZ note:  • that current regulatory arrangements are comprehensive in requiring food packaging to be safe, including providing a basis for limiting the migration of packaging chemicals into food, and  • increases in the sensitivity of chemical assays which show the presence of migrating packaging chemicals in food does not of itself indicate a health risk and is not a sound basis for proposing regulatory change, particularly if it is of a more prescriptive nature.  4. FSANZ adds phthalates to the regular cycle of the Australian and New Zealand Total Diet Studies to track exposure over time and assess whether the outcomes of P1034 have served to reduce chemical migration from packaging into food. | Australian Food and Grocer Council (AFGC) | Noted.  A targeted follow up survey of DEHP and DINP plus five additional plasticisers in Australian foods found that estimated dietary exposures are below the tolerable daily intakes (TDIs) for these substances and are not of concern for human health.  A recent survey of packaging chemicals including phthalates, printing inks and photoinitiators in New Zealand foods also found that dietary exposures to these chemicals are low and not of concern for human health.  The overall conclusion based on the available data is that the human health risk posed by chemical migration from packaging into food available in Australia and New Zealand is low.  FSANZ will also continue to monitor CMPF issues as they emerge and will consider appropriate management options if required. This will include phthalates. FSANZ has in place an emerging and ongoing issues protocol in order to effectively manage new risks in the food supply. This also captures CMPF.  These activities will continue to be communicated through the FSANZ website, publications and social media. |
| NZFGC considers the process undertaken by FSANZ in the course of reaching the current Call for Submissions has been excellent. It has been focussed, measured, inclusive and very well managed. We have appreciated being included throughout.  The risk profiling indicated that most chemicals used to produce food packaging were unlikely to pose a public health and safety concern, predominantly because of their extremely low levels of migration into food. This conclusion was supported by information on hazard and dietary exposure for a large number of food packaging chemicals. It was also consistent with the findings of analytical surveys investigating the presence of specific packaging chemicals in Australian and New Zealand foods. | New Zealand Food and Grocery Council (NZFGC) | Noted. |
| While food businesses are required to use safe packaging in both Australian and NZ food safety legislation, MPI believes that the Food Standards Code should continue to be the best place to set requirements for managing risks from chemical migration from packaging materials into food. This includes adding any limits arising from the phthalate research. This will provide consistency in both New Zealand and Australia for import and export of foods and packaging materials.  Attached an updated version of SD1 relating to legislation relevant to New Zealand packaging. | New Zealand Ministry for Primary Industries (NZMPI) | Noted.  FSANZ has not identified a need to set maximum limits for CMPF. Rather, a non-regulatory approach is appropriate and supported by FSANZ’s risk assessment.  The new information on NZ legislation has been included in Supporting Document 1 of the 1st Call for Submission Report (June 2016). |
| We support limited regulation.  Further regulation is not required if food safety is defined as meeting suitable existing regulations from the European Union and United States Food and Drug Administration. The proposed sections are found in the submission detail.  At a basic level we would define packaging in New Zealand as:   * Packaging manufactured inside NZ which is then filled with product in NZ (Locally made packaging) * Packaging manufactured outside NZ which is then filled with product in NZ. (Imported packaging) * Packaging manufactured outside NZ which is then filled with product before being imported into NZ. (imported pre-packaged products)   NCI considers that any final framework and/or regulations determined by FSANZ to mitigate any potential risk posed by chemical migration from packaging into food (CMPF) should capture all packaging, not just locally made packaging or locally filled packaging. It needs to also capture imported fully-packaged products.  It is essential that packaging standards and enforcement are applied consistently on all packaging to ensure that domestic producers are not indirectly cross-subsidising / shielding imported goods. Without that consistent obligation ‘market forces’ will logically operate to increase the consumer’s exposure to unregulated food at the expense of the regulated packaged food. | NCI Packaging  Packaging Council of New Zealand | Noted.  Proposal P1034 is not reviewing packaging per se, but rather the potential for CMPF. The Code applies to both domestically produced and imported food, and as an extension of this, to both domestically packaged and imported packaged products. The suggested distinctions of different types of packaging are useful and will be considered in any future packaging information that is produced by FSANZ.  The consistent application and enforcement of the Code is the responsibility of the State and Territory governments, the Department of Agriculture and Water Resources at the border and the Ministry of Primary Industries in New Zealand.  FSANZ’s risk assessment and management options captured all CMPF arising from use of either domestic or imported packaging. |
| There are currently no barriers preventing importers bringing in food contact film, regardless of whether it complies with AS2070 or not, and regardless of the type of plasticisers used, or the level of plasticisation. The industry would like to see this addressed and there is potential scope to develop a global migration limit in relation to packaging films.  Chemicals falling within the category of low risk could be managed through the use of voluntary industry guidelines.  The Industry Code is therefore currently being updated and incorporated into the vinyl industry’s PVC Stewardship Program. The new ICP will restrict the use of ortho-phthalate plasticisers such as DEHP and DINP in vinyl food contact packaging films.  Under the PVC Stewardship Program, packaging film manufacturers will be required to report compliance with this Industry Code and may be audited periodically. The new Code is expected to be published before the end of 2016, and could be incorporated into a guideline for PVC food contact packaging films under the FSANZ Proposal.  The local vinyl packaging industry is confident that the risk of chemical migration from packaging to food is well understood, managed and controlled. However, there is concern that producers of imported materials may not have the same level of management or control. | Vinyl Council of Australia | Noted.  FSANZ’s risk assessment did not indicate any need to develop a global migration limit for packaging films.  Food businesses (including manufacturers, caterers, importers and retailers) importing (or using imported) food contact film must ensure that the film is fit for purpose and does not contaminate the food.  The reference provided to the PVC Stewardship Program will be a useful resource which can be included in guidance material. |
| The quality and safety of packaging material used in Australia may in some part be due to legislated requirements and standards in other countries, such as the United States of America. However, food may be imported from anywhere in the world and imported foods may use packaging material that is not subject to the same standards. In the absence of specific limits for certain contaminants, regulatory agencies can only rely on general offences. Suitable guidance material on contaminants in this respect may assist regulatory agencies as well as businesses.    In relation to the assessment of risks to the Australian public from perfluorinated chemicals (PFCs) in packaging, it is noted the sample size from the 24th ATDS was relatively small at 50 composite samples.  It is also noted that the controls to minimise exposure to those PFCs that may accumulate appears mostly to be based on control measures in the United States of America.  As such, further monitoring and assessment may be needed in Australia to determine if the use of these chemicals in oil and water repellent coatings on food packaging continues and if the chemicals present a risk to consumers. | Queensland Health | Noted. FSANZ has not identified a need to set maximum limits for CMPF. Rather, a non-regulatory approach is appropriate and supported by FSANZ’s risk assessment.  The public health and safety issues raised have been addressed above in FSANZ’s response to the AFGC submission.  FSANZ will also continue to monitor CMPF issues as they emerge and will consider appropriate management options if required. This will include phthalates and PFCs. |
| MPI supports the aims of the proposal to increase awareness and understanding of the potential risks posed by food packaging. MPI agrees while there are potential risks from Chemical Migration from Packaging into Food (CMPF), the risks are generally accepted to be low and therefore do not require a prescriptive approach. | NZMPI | Noted and the public health and safety issues raised have been addressed above in FSANZ’s response to the AFGC submission |
| The Food Authority supports FSANZ undertaking further work in regard to the specific compounds, diethylhexyl phthalate (DEHP) and Diisononyl Phthalate (DINP) noting the results from the TTC analysis for these two compounds. The Food Authority will re-consider its view on these two compounds once further information is available. | NSW Food Authority | Noted and the public health and safety issues raised have been addressed above in FSANZ’s response to the AFGC submission. |
| We believe a sound approach would be to adopt a system that would ensure compliance by relying upon the standards already developed and used by many countries as evidence of safety. Specifically, we believe a demonstration of compliance with the requirements for food-contact materials in the United States (U.S.) or the European Union (EU) would not require an enormous regulatory burden, but would set a basis of safety for food-contact materials.  We would not support the adoption of an entirely new regulatory scheme for food-contact substances that is unique to Australia and New Zealand. Such a system would prove costly to FSANZ to develop and to industry to come into compliance. These costs would not bring along with them added health and safety benefits, as the systems in place in the U.S. and the EU are comprehensive and highly protective of human health. | The Society of the Plastics Industry | Noted. FSANZ’s risk assessment has not identified a need for a regulatory measure at this time. |
| Food packaging is essential and ensuring the balance between ensuring the safety of consumers and the regulatory effort required by businesses in relation to food contact materials is of paramount importance.  DuPont supports harmonised, risk-based approaches to management of food contact materials and articles,  where risk-based approaches take exposure potential as well as hazards into account. DuPont highlights the current lack of consistency between country regulatory requirements and the increased associated compliance costs and reduced ability to commercial products globally. We support mutual recognition of applicable data and the collaboration between countries in developing harmonised approaches to the management of food contact materials. | Dupont | Noted.  FSANZ used overseas data in its risk assessment of more than 1300 food contact substances identified for assessment. Based on this assessment, FSANZ has not identified a need for regulatory measures at this time.  However, a part of a non-regulatory approach to managing the potential risks from CMPF, FSANZ has identified the need for a food packaging information guide which would be a consolidated source of information related to packaging of food sold in Australia and New Zealand. The guide will include a description of international regulatory requirements.  Industry will be encouraged to take international regulations into account as part of their own risk management plans for CMPF. |
| Victoria continues to receive queries from SMEs regarding requirements for `food grade’ packaging and where to source this information. This lack of knowledge by certain industry sectors appears to be supported by FSANZ’s findings.  Currently there is not a suitable standard or document that can be referred to for guidance on food packaging materials. As a regulator, the Department of Health and Human Services notes that this is problematic, particularly if enforcement action relating to the inappropriate use of packaging were to be pursued. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources. | The Code does not define what a ‘food grade’ is; rather, Commonwealth, State and Territory laws apply the Code for their purposes and these laws also determine what a food is for the purposes of the applied Code.  Therefore, enforcement agencies may be better placed to define ‘food grade’ in relation to packaging.  To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. The guide will be a general resource for a range of stakeholders and will address identified gaps in awareness and knowledge of CMPF, particularly for SMEs. However, the guide will not include specific information for industry in relation to compliance with the Code. This is not within the remit of FSANZ’s role in the food regulatory system. |
| Potential health and safety risks arising from food produced using modified atmosphere packaging, active and intelligent packaging and nanomaterials were excluded from the scope of Proposal P1034 as these matters will be the subject of a subsequent examination. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources. | These matters will be addressed in a future project at FSANZ. |
| Code/Food Acts | **Raised by** | **FSANZ response** |
| Packaging suppliers including agents need to be more responsible for what they manufacture and or sell. Food manufacturers do not use unsafe packaging materials intentionally, the financial risk is enormous. Packaging manufacturers, particularly agents, often represent suppliers that are based in Asia, are unfamiliar with EU or FDA requirements and may make statements about compliance which cannot be substantiated. These parties are generally not accountable when packaging proves to be non-compliant. This issue should be addressed more directly as this is the core area of CMPF concerns.  Regulations that impose a responsibility on the packaging supplier or agent in the Food Acts provisions regulating the sale of food packaging in Australia and New Zealand for disclosure of ingredients going into packaging would be a significant help. From this, compliance can be evaluated. | Nestle | Noted.  As explained in the 2nd CFS Report, 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. Food businesses are therefore required to ensure that the packaging used is fit for purpose and does not contaminate the food.  The overall conclusion based on the available data is that the human health risk posed by chemical migration from packaging into food available in Australia and New Zealand is low. |
| NZFGC does not support either of these options on the basis of duplication, ineffectiveness and inconsistency.  Although it might raise awareness, a standard in the Food Standards Code would likely duplicate ‘duties of care’ already placed on food manufacturers under the food Acts and would not provide the coverage necessary to packaging suppliers.  Inconsistency refers to the time taken to amend food Acts and the inconsistency that exists during that period. We understand, for example, that some States took almost a decade to implement the Model Food Act provisions. New Zealand took over a decade to initiate, develop, draft and implement its new food legislation (the Food Act 2014). These processes do not lend themselves well to timely amendment for what would be only partial coverage of the packaging supply chain. | NZ Food and Grocery Council | Noted.  Overall, the assessment work for the proposal P1034 showed that the human health risk posed by CMPF from food available in Australia and New Zealand was low. Therefore, introducing further regulatory measures was unnecessary. |
| The Food Act provisions need to provide a sufficiently broad scope for further detail in regulation where needed. Food Acts have limited ability to make standards that apply directly to packaging businesses, but have considerable scope for control of packaging used for food and requirements for food businesses.  It may help food businesses awareness of their responsibilities and provide clarity, to include general requirements for packaging safety and suitability in the Code that are consistent with the clauses in the various Food Acts. Most businesses will be familiar with the Code but may not be aware of the relevant clauses in the Food Acts or of the existence of other documents including Codes of Practice (CoPs) or guidelines. A general provision in the Food Code, consistent with the Food Acts, provides a clear link to the MLs in the Code that relate to packaging. If there were no such requirement, there could be questions regarding the appropriateness in the Code of MLs that relate to packaging. | NZMPI | Noted.  The amendment or otherwise of the Food Acts is outside of FSANZ’s remit and remains a matter for Governments.  To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide with the intention of helping food businesses to be aware of their responsibilities regarding CMPF |
| Section 38 of the Queensland *Food Act 2006* includes the following offence ‘A person must not sell packaging or labelling material that, if used for the purposes for which it was designed or intended to be used, would make or be likely to make food unsafe.’  This may be able to be applied for some acute health risks but in practice is may be difficult to prove in court for chronic exposures to chemical contaminants. In many cases it would be easier and perhaps more appropriate to prove contamination made the food unsuitable. As such, consideration could be given by jurisdictions to including a similar offence the sale of packaging and labelling material that would make food unsuitable. Consideration could also be given to legally defining ‘food grade’ packaging to give greater clarity to businesses when sourcing packaging. | Queensland Health | Noted. The issue of legally defining food grade has been addressed above in FSANZ’s response to the submission by The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. |
| Suggested that additional health and safety protection might be gained by the adoption of a system of compliance of food-contact materials with the requirements in place in the U.S. or the EU. The added protection that will come with the adoption of such a system would come at little cost to FSANZ to develop, as the U.S. and EU systems are comprehensive and could be easily cross-referenced in the Code | The Society of the Plastics Industry | FSANZ’s risk assessment does not support the need for such a regulatory measure as the FSANZ risk assessment determined that there is a low risk from CMPF at present.  However, industry adoption or voluntary compliance with key overseas regulations enables compliance with the Food Act provisions (which require food to be safe and suitable) and existing Code requirements. The identified gaps in knowledge from SMEs will be addressed by information material developed by FSANZ. This will include references to international regulatory requirements for food packaging materials and will suggest that industry consider these regulations when developing their own risk management plans for CMPF. |
| The current Standard 1.1.1-10 Packaging requirements need amendment. The requirement relating to packaging and articles (1.1.1-10 clause 11), if taken into the mouth, should be removed from the Code as it is more appropriate that this be under the Australian Consumer Law.  There is scope to improve the Food Acts provisions regulating the sale of food packaging in Australia and New Zealand by some clarification regarding the wording, “packaging or labelling material that if used for the purposes for which it was designed”. The offences that include the words “ought reasonably to know” would be supported by an information/awareness program of the kind discussed in this Proposal. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources | Noted.  This is in the first instance a matter for the Governments responsible for the Food Acts and the Australian Consumer Law. |
| Integrating US and EU approaches in the Food Acts would convey a strong message in the internal market and would facilitate export and import of products to/from other markets. | Sealed air | Noted  FSANZ also noted that the Food Acts and Code are outcome based and do not prescribe how a business should achieve safe and suitable food. |
| Reviewing the Food Act provisions to regulate the activities of the food packaging industry might help to provide clarity about their responsibilities in regard to CMPF and product safety.  A change in the Food Act provisions to include packaging materials might also encourage the sharing of information in regard to compliance of raw materials and packaging products along the supply chain. | Scion | Noted. See responses above. |
| Public health and safety | **Raised by** | **FSANZ response** |
| NZFGC would support a regulatory measure for DEHP and DNIP if the exposure assessment FSANZ is currently conducting demonstrates a high exposure that needs to be addressed. | NZFGC | Noted. FSANZ has conducted a range of activities to investigate the potential human health risks from migration of chemicals in packaging into food. This work has included analysis of a USFDA database of over 1300 food contact substances, as well as several analytical surveys of packaging chemicals in Australian and New Zealand foods. The overall conclusion based on the available data is that the human health risk posed by chemical migration from packaging into food available in Australia and New Zealand is low. In particular, a targeted follow up survey of DEHP and DINP plus five additional plasticisers in Australian foods found that estimated dietary exposures are below the tolerable daily intakes (TDIs) for these substances and not of concern for human health. |
| DINP, a high molecular weight ortho-phthalate, is not classified as hazardous. It should be noted that NICNAS has recently assessed and reported that “the public health risks for the general population (without occupational sources) and children (with or without mouthing toys) from all exposure sources (including indirect exposures via the environment) to [DINP] are considered low, based on the evaluation of margins of exposure (MOEs). | Vinyl Council of Australia | Noted. See response above. . |
| The Food Authority acknowledges the comprehensive risk assessment conducted by FSANZ as part of Proposal 1034. The Threshold of Toxicological Concern (TTC) analysis conducted by FSANZ on 1300 chemicals concluded there is a low risk arising from CMPF. | NSW Food Authority | Noted |
| Support FSANZ’s conclusion that, with the exception of two phthalates, CMPF represents a low risk to public health and safety. | The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. | Noted. See FSANZ’s response above to the NZFGC submission. |
| Question the need to reform food contact regulations based solely on the findings from the 24th ATDS. We note the relatively high quantities of food required to be consumed to reach daily TDI values for DEHP (0.5 - 0.7 kg of food tested consumed daily) and DINP (0.6 kg of food tested consumed daily). | Dupont | Noted. See responses above, |
| Control measures and market information | **Raised by** | **FSANZ response** |
| From our perspective, the conclusion that a small number of manufacturers represent a high market share is incorrect, in our market segment there is a significant amount of food packaging materials that are imported from a large number of countries, including less developed countries. We also believe that some of the imported product is misclassified within the tariff regime, obscuring the true level of importation.  We maintain a watching brief on developments in the European and US food safety agencies, to guide the evolution of our products and the materials that we use to manufacture them. We adopt a best practice approach to ensure our products comply to the globally accepted regulations and practices to ensure food safety is key to Australia/NZ and Australian/NZ industries to remain relevant and to maintain its reputation as a safe food leaders. IPG has as a result removed Phthalate from our production and processes. We conduct routine tests as part of a QA program to ensure Zero Phthalate in the films that we produce. | Integrated Packaging | Noted. FSANZ welcomes further information about the classification of imported packaging materials. |
| Agrees with FSANZ’s analysis of control measures and market information about how chemical migration from packaging to food is being approached in Australia and New Zealand. | NZ Food and Grocery Council | Noted. |
| FSANZ’s analysis of control measures is representative, for domestically produced packaging. However, given that both jurisdictions have significant finished (pre-packaged) imports, we are not assured the same measures are being applied to products sourced from outside Australia and New Zealand. | NCI Packaging  Packaging Council of New Zealand | Noted. The response to the NZFGC under Public Health and Safety heading also applies to imported materials/packaging.  The overall conclusion based on the available data is that the human health risk posed by chemical migration from packaging into food available in Australia and New Zealand is low.  Food sellers are required to ensure food in contact with packaging is safe. Only materials that are fit for their intended use and are not likely to cause food contamination must be used. This includes imported foods and packaging materials sourced from outside Australia and New Zealand. |
| Have implemented Good Manufacturing Practice (GMP) that meets the regulatory requirements across the globe. Food packaging converters ensure compliance with US or EU standards. Also apply HACCP Management System ISO 9000 to ensure meeting hygiene and quality standards. | Sealed Air | Noted |
| Our members have implemented rigorous good manufacturing practices (GMP) that meet the regulatory requirements for GMP across the globe. GMP considerations form the basis of any sound food packaging manufacturing program and fit squarely within the general safety paradigm, the standard currently in place in Australia and New Zealand. When marketing products in Australia and New Zealand, our members are compliant with U.S. or EU standards (including GMP considerations), which are generally accepted across the industry and by governments around the world as a sufficient basis for establishing safety and suitability of a given food packaging material.  The purpose of GMP programs in the production of food-contact materials is to reasonably ensure that the packaging product will not adulterate food or lead to any public health or safety concerns. | The Society of the Plastics Industry | Noted. |
| The information collected by FSANZ looks reasonable in regard to regulatory and non-regulatory measures used. However, it should be considered that the survey solely relied on voluntary information and therefore the figures given might not portray the whole picture.  Also it should be noted that it is not really possible for packaging material suppliers and converters to claim that their packaging is compliant unless they know from their customers how the packaging is going to be used and complete tests accordingly (e.g. what product it contains, temperatures of use, and length of exposure). | Scion | FSANZ noted that the information provided was based on self-reported data. A range of methods were used to gather as broad a representation as possible of control measures used in the packaging supply chain.  State and Territory Food Acts – through which the Code is given effect and through which CMPF is primarily managed – place the onus on those businesses that purchase packaging from material suppliers or converters to ensure that it is fit for purpose and does not contaminate food. |
| Agreed that FSANZ’s analysis of control measures and market information accurately represents how CMPF is being controlled in Australia and New Zealand. | The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources.  Nestle  Scion  The Society of the Plastics Industry  Sealed Air | Noted. |
| Risk management options (general comments) | **Raised by** | **FSANZ response** |
| We suggest FSANZ adopt Option 1: Status quo in combination with Option 3a: Education/ awareness/ information programs and Option 3b: Industry self-regulation by industry standards or code of practice.  In more detail, this would see management of chemicals used in food packaging primarily addressed by maintaining the status quo and still referring to US and EU positive lists. By also implementing Options 3a and 3b, FSANZ can improve the awareness of all stakeholders (in particular SME’s which were identified as the stakeholders with potential gaps in the regulatory knowledge and awareness of regulations from CMPF), and deliver the key information to downstream users through Declaration of Compliance (DoC).  Finally we suggest FSANZ conducts risk-based assessments on high risk substances which are identified through routine surveillance or high topic tracking.  Training/awareness and risk-based decisions should be included with management of CMPF. Consumers should also be made aware of regulatory and risk mitigation measures enforced by FSANZ, along with general outcomes of surveillance and monitoring outcomes, to support compliance efforts completed by industry. | Dupont | Noted. FSANZ publishes the results of all its surveillance activities on its website and communicates outputs (and their significance) at a range of fora. |
| *Option 1: Status quo* |  |  |
| Not supported.  The data collected by FSANZ has demonstrated that chemical migration from packaging into food is low, albeit with further work required to characterise any potential public health risks posed by the phthalates DEHP and DINP. The AFGC agrees that the initial consultations have highlighted gaps in knowledge of chemical migration from packaging into food and understanding of how to address it. As such, the AFGC strongly supports option 3a of providing education, awareness and information programs to industry. | AFGC | Noted.  FSANZ has completed further work characterising potential health risks posed by the phthalates DEHP and DINP (see SD3 of this report).  Therefore, following application of the graduated risk management approach, FSANZ has not identified any chemicals that meet the criteria for a high risk chemical nor any evidence that the Code needs to be strengthened. To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| The status quo, or laissez-faire approach ensures that there is little incentive for suppliers of food contact packaging to pay any regard to CMPF, particularly because of the low level of awareness of this issue in the food processing and consumer markets. As a result there are packaging products on the market which contain phthalates at levels far beyond safe levels and propose potential risks to food users. | Integrated Packaging | Noted.  FSANZ has conducted a range of activities to investigate the potential human health risks from migration of chemicals in packaging into food. This work has included analysis of a USFDA database of over 1300 food contact substances, as well as several analytical surveys of packaging chemicals in Australian and New Zealand foods. The overall conclusion based on the available data is that the human health risk posed by chemical migration from packaging into food available in Australia and New Zealand is low. |
| NZFGC considers that a status quo option does not address potential public health and safety issues (particularly in relation to phthalates), unknown risks and the other issues of lack of awareness and clarity in the Code. However, neither do all these matters require a regulatory solution.  The information appropriate to include in an awareness and education approach needs to be developed in liaison with a range of agencies to ensure appropriateness and clarity for each business in the supply chain. This may involve a range of products and processes tailored to the differing supply chain points. In our view this requires a separate project. | NZ Food and Grocery Council | These issues have been addressed in response to FSANZ’s response to AFGC submission on this option. |
| The option of status quo and abandoning the proposal does not achieve the regulatory certainty needed. MPI agrees that (as per the Call for Submissions paper) that Submissions to the consultation paper indicated that there is lack of clarity and certainty with the Code for food businesses.  Control practices are not currently consistently applied across industry and gaps in the awareness and management of CMPF particularly for SMEs. Suitable guidance materials and MLs for identified high risk chemicals should be considered further. | NZMPI | The Food Standards Australia New Zealand Act 1991, section 56 permits two options to finalise the Proposal depending on the results of the assessment. Amendments to the Code or other regulatory options would be considered if CMPF was likely to increase the risk of food contamination or increase exposure to packaging chemicals and thus indicate that current regulations for food packaging were insufficient to protect public health and safety. If the assessment showed that amendments to the Code and other regulatory options are no warranted having regard to, among other things, the risk assessment , then the process to finalise the proposal under the FSANZ Act is abandonment.  Overall, the assessment work for P1034 showed that the human health risk posed by CMPF from food available in Australia and New Zealand was low. Therefore, introducing further regulatory measures was unnecessary and the Proposal was abandoned. |
| For multi‐national companies like Clorox, the status quo option works well. We prefer that the status quo option remains. | The Clorox Company | Noted. |
| The status quo option does not improve the current situation. There is currently a lack of clarity and certainty with the Code for food businesses, and gaps in the awareness and management of CMPF, especially amongst SME enterprises, food manufacturers and food regulators. | Queensland Health | Noted.  Evidence of gaps in awareness and management of CMPF was provided in the June 2016 Call for Submissions. To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| Agree with FSANZ’s statement, “There is a lack of clarity and certainty with the Code for food businesses, and gaps in the awareness and management of CMPF”. However, the status quo option does not address this. An information/awareness program would more appropriately support option 4 rather than be used as a standalone measure. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources. | Noted and addressed in FSANZ’s response to the AFGC and Queensland Health submission. |
| We see no benefit in any programme which specifically educates or informs the consumer. Consumers are entitled to assume food they get is fit for purpose without having to understand the underlying science or undertake their own checks.  Our suggestion would involve a regulatory approach and therefore information and communication would be appropriate to that. | NCI Packaging  Packaging Council of New Zealand | Noted  The Food Acts – through which the Code is given effect and through which CMPF is primarily managed – place the onus on food businesses to ensure that they supply food that is safe and suitable.  To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide and this will include consumers. |
| Based on the information presented in the Proposal, many in the vinyl value chain are of the view that, of the four risk management response options proposed, maintaining the status quo is currently justified.  Local packaging manufacturers and raw material suppliers show good awareness and uptake of international packaging regulations.  Feedback in the vinyl sector suggests that major food packaging manufacturers are aware of their responsibilities when it comes to migration and contaminants into the packaged food and as such, take measures to ensure this is not occurring. | Vinyl Council of Australia | Noted  Whilst many major food packaging manufactures are aware of their responsibilities, FSANZ has become aware through its research (both qualitative and quantitative) that there are gaps in understanding and awareness of food safety requirements (pertaining to packaging) and packaging contaminants have been found in some foods. |
| We support the official recognition by ANZ Code of US FDA and/or EU legislations as the most appropriate solution to the issue. A major problem of the status quo option is the lack of the comprehensive regulation of food packaging with legal validity that limits the enforcement measures to contrast negligence and unsafe practices. Food packaging suitability and safety in ANZ is assured by the application of relevant US FDA and EU legislations, which are currently referenced only by a voluntary standard (AS2070).  An effective information program could be represented by participation to international partnership programs organized e.g. by the European Union for the development and exchange of knowledge on specific matters.  The Government should support the development of national scientific competences to address CMPF and the implementation of procedures for the management of risk related to chemicals in food packaging.  AFGC/NZFGC and packaging peak bodies are the most appropriate organisations to undertake this program. | Sealed Air | Noted.  The Code does not reference specific voluntary standards for packaging materials (eg, AS2070). The latter can be referenced in a future packaging information guide. |
| We believe that the status quo approach under the current law in Australia and New Zealand is adequately protective of human health and safety because food packaging presents a very low risk to the safety of food, and, thus, to public health in general. Nevertheless, we would not object to the adoption of a more formal system to provide further protection to consumers in Australia and New Zealand. By choosing to incorporate the U.S. and EU systems formally into law in Australia and New Zealand, this additional protection will be gained at very little cost to FSANZ.  Because Standards Australia currently administers nonbinding guidance for packaging, we believe that Standards Australia is well-positioned to serve as the lead organization for any potential education or information program for industry participants. We would be glad to assist Standards Australia (or another designated peak organization) with such efforts. | SPI | Noted. |
| In our opinion there is room for improvement in the current code in the areas of ensuring public health and safety and in providing more clarity and guidance for food businesses, packaging suppliers and raw material manufacturers. Therefore, abandoning this proposal is not a sensible option.  A benefit of information/awareness programmes is that they target the whole supply chain including the consumers. Educated consumers are able to drive change by making informed choices.  However, one challenge will be to engage those who are not interested. Some businesses are already well informed and ensure that their products are safe; whereas, others are either not aware or do not see the need to act. Information/awareness programmes might not reach those companies.  FSANZ and AFGC/NZFGC NZFSC and packaging peak bodies are suited to undertake such a program. However it might be worthwhile to include industry advisory groups, as well. | Scion | Noted.  A future packaging information guide will assist in addressing information/awareness for SMEs but FSANZ acknowledges that it cannot ensure that it will reach all businesses. |
| The provision of general information to consumers, particularly with regard to the outcome of the risk assessment conducted by FSANZ, will be helpful to better inform consumers and increase understanding of the level of risks posed by CMPF.  Such awareness programs will also increase awareness within industry but may not be sufficient to achieve the level of awareness sought.  Consumer advocacy organisations should also be engaged in consumer awareness activities. | Dairy Goat Co-operative (N.Z.) Ltd, (abbreviated as ‘DGC’). | Noted  Stakeholder consultation for P1034 identified significant gaps in industry awareness of the control measures needed for CMPF, mainly for small-to-medium enterprises (SMEs). Therefore, development of a food packaging information guide was proposed as a non-regulatory risk management approach. Development of the guide was supported in submissions received to the 2nd Call for Submissions paper. Provision of information is a function of FSANZ under the Food Standards Australia New Zealand Act 1991. |
| Nestlé does not consider that there would be any significant gains in better control of CMPF with this option.  For companies following internationally recognised regulations, requests to packaging suppliers for details ingredient information, may be met with responses indicating that they are not willing to divulge ingredients used to make their packaging, or on occasion, it may be found during investigating a new packaging supplier, that suppliers may be using ingredients at levels considered unsafe. It may be the case that other food packers could be using these materials without an understanding of the apparent consequences. This lack of standards or a level playing field could allow questionable health issues to arise in Australia and NZ. | Nestle | Noted. |
| Major risks presented by adopting Option 1: Status quo orient around some sectors, for example SMEs, which may still experience regulatory knowledge gaps. This could be minimised by increased risk-based awareness efforts along with targeted monitoring and surveillance activities. The use of Declaration of Compliance (DoC) could offer downstream users with key information coupled with greater transparency. | Dupont | Noted. |
| *Option 2: Prescriptive approach* |  |  |
| Not supported.  The AFGC concurs with FSANZ’s assessment that a purely prescriptive approach to managing chemical migration from packaging into food is not warranted in Australia or New Zealand. The AFGC does not consider that the evidence gathered to date forms sufficient argument, or basis, for introducing more prescriptive requirements into the Code. | AFGC | Noted.   Overall, FSANZ’s assessment work for proposal P1034 confirmed that the human health risk posed by CMPF from food available in Australia and New Zealand was low. Therefore, introducing further regulatory measures was unnecessary. |
| Building the necessary resources to administer a prescriptive regime will be very time consuming and costly, and will impose unnecessary burdens on the industry. It would also introduce a long period of uncertainty whilst the process was rolled out. | Integrated packaging | Noted. |
| NZFGC does not support a prescriptive approach, on the basis that it is largely ineffective in that it diverts huge resources into areas of negligible risk for negligible benefit without a comprehensive result.  Option 2 mirrors the USA and EU approaches which assess chemicals on a substance-by-substance basis irrespective of risk. It is likely that these ‘approaches of the past’ have built up out of tradition over many decades. None are succeeding in terms of coverage, comprehensiveness or currency. This is primarily due to not being able to accommodate the multitude of developments being undertaken in the packaging and related industries supply chain (not the least recycling), the extensive number of chemicals used at the various, sometimes quite remote, steps prior to the use of packaging by food manufacturers (an estimated 6,000 chemicals in printing inks alone) and the absence of data on human impacts. | NZ Food and Grocery Council | Noted. |
| MPI agrees while there are potential risks from CMPF, the risks are generally accepted to be low and therefore do not require a prescriptive approach. MPI also notes that there may be legal issues in recognising other countries’ regulations (such as those of the EU and the US) in the Code and that these do not cover all packaging materials. | NZMPI | Noted. |
| The prescriptive approach will result in an increased cost for the consumer, industry and government. Multi‐national companies like Clorox, has adequate knowledge of the risks from CMPF and have adopted the US approach and the Australian Standard (AS 2070‐1999). Thus a prescriptive approach is not required. | The Clorox Company | Noted. |
| No new regulations are required, as the USFDA and EU approaches (typically used in the larger packaging companies in New Zealand) are already prescriptive. To introduce new regulations to the Australasian market duplicates existing regulations adding unnecessary compliance and associated costs. However, we suggest that a clearly defined framework of current relevant US and EU regulations should be established, and by adopting these regulations as FSANZ regulations would provide appropriate controls for CMPF. The use of a specific set of EU and USFDA regulations would provide industry wide conformity and compliance for companies already using these standards and also capture those small to medium enterprises (SME) and importers who may represent an unknown risk in terms of CMPF.  We have defined the applicable EU and USFDA regulations in Appendix 1 of our submissions. | NCI Packaging  Packaging Council of New Zealand | Noted and addressed in response to the AFGC submission. Relevant international regulations will be covered in the proposed packaging information guide. The guide will encourage companies to take international regulations into account as part of their own risk management plans for CMPF. |
| In the absence of evidence of regulatory failure in this area, the departments would anticipate that the costs to industry and regulators of including more prescriptive or onerous requirements in the Code would outweigh the benefits. | The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. | Noted. |
| We consider that the low risk from CMPF pointed out by FSANZ assessment is, largely, the result of the application of USFDA and/or EU legislation by the main packaging producers in ANZ market and therefore it derives "de facto" from the application of a prescriptive approach. For this reason, a new proposal should maintain a reference to those legislations that can cover most of the aspects of packaging (different materials, coatings, inks, adhesives) and are extensively adopted by the ANZ packaging industries. | Sealed air | Noted. |
| The creation of a separate system in Australia and New Zealand would only lead to burdens on the government’s resources from the creation and maintenance of a separate prescriptive system that would not add any additional protection for public health. In addition, packaging suppliers develop their products to comply with global requirements. The addition of a new regulatory scheme in Australia and New Zealand would drive changes to existing products that are currently safe and suitable for use in food-contact applications. Because these existing products are already safe, the resources expended by suppliers to change their products to align with yet another regulatory system are unnecessary. | The Society of the Plastics Industry | Noted. |
| The adoption of a prescriptive approach is not regarded as the most appropriate option, however in the following pros and cons for such an approach are given:  Pro:  Positive and negative lists are easy to follow and provide clear rules for companies in regard to food contact compliance.  Companies exporting their products to the US and/ or Europe need to show compliance with these regulations anyway. Therefore, it would make it easier and cheaper for these companies if the decision was made to adopt either the US and/or EU regulation.  Con:  The adoption of either the US and/or EU regulations to Australia and New Zealand might be a disadvantage for small companies. The requirements listed in these regulations are quite extensive and usually require a wide variety of compliance testing. This might pose a financial burden on small companies without necessarily increasing health and safety of the public.  There is a risk that adopting those stringent and inflexible regulations might pose a barrier to innovation for companies in Australia and New Zealand. As the surveys conducted by FSANZ on CMFPS showed, the estimated exposure to packaging chemicals detected in Australian and New Zealand foods and beverages are below internationally recognised safe levels and present a negligible to low risks for our population. Therefore, it might be possible to adopt an approach that is less rigid than a prescriptive approach allowing more flexibility in regard to new and innovative packaging materials. | Scion | Noted and addressed in response to the AFGC submission. |
| Does not support a prescriptive approach. | Dairy Goat Co-operative (N.Z.) Ltd, (abbreviated as ‘DGC’). | Noted. |
| Nestlé does not consider a prescriptive approach as the best answer. It would be advantageous if legislation were introduced to assist food manufacturers to obtain information from the packaging supplier on the packaging ingredients which would then enable the food manufacturer to evaluate the material for safety. It is often difficult to obtain a complete list of ingredients from some packaging suppliers. To enable food manufacturers to be responsible for packaging safety, requiring suppliers to provide complete information to an agreed standard would enhance this process. | Nestle | Noted. FSANZ is aware that the AFGC developed a Product Information Form (PIF) that should address these issues. |
| If a prescriptive approach is considered to be the most appropriate option, DuPont highlights the resource requirements of obtaining approvals in individual countries, with the potential to cause delay. We note the direction of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) reforms, towards accepting overseas assessments to avoid duplicated regulatory effort. We would encourage FSANZ to support harmonisation of data needs and acceptance of overseas regulations, in particular EU and US requirements. | Dupont | Noted. |
| *Option 3: Non-regulatory options*  *3a: Education/Awareness/Information programs* |  |  |
| The AFGC supports and is willing to assist in facilitating an education, awareness and/or information program for industry to address specific gaps in knowledge and awareness of chemical migration from packaging into food.  It should be clearly noted that the AFGC only supports education, awareness and information programs targets to industry. The AFGC is concerned that any such program directed towards consumers (regardless of its scientific rigour) is likely to result in unwarranted concerns being raised regarding particular packaging materials. | AFGC | FSANZ notes the AFGC’s position on this option in regard to consumers; however, FSANZ agrees with the NZMPI that information and awareness programs could be targeted at the responsibilities of food businesses, particularly SMEs to use safe packaging materials and the regulatory requirements. It would also be helpful to provide more general information to consumers as there is both huge interest and confusion generated internationally.  FSANZ would encourage the AFGC to also produce a dedicated facts sheet for consumers demonstrating the extent that the food industry undertakes to produce safe food from the variety of packaging materials. |
| Education and the provision of information about CMPF is an important component in any risk management scheme that is introduced to address this issue.  However, it is important that the industry is in a position to respond effectively to consumer awareness, so that consumers are able to exercise choice, rather that leaving the responsibility to consumers to motivate such a response from the industry | Integrated packaging | Noted. |
| Awareness and education are vital tools for communicating requirements and expectations with or without regulatory interventions. Such tools can assist with alerting the consumer (the manufacturer in this instance) to the need for specifying requirements to their packaging supplier that refer to internationally accepted standards and identifying unacceptable packaging materials.  The information appropriate to include in an awareness and education approach needs to be developed in liaison with a range of agencies to ensure appropriateness and clarity for each business in the supply chain. This may involve a range of products and processes tailored to the differing supply chain points. In our view this requires a separate project.  We agree that FSANZ, the AFGC/NZFGC and packaging peak bodies are the most appropriate organisations to undertake a program of education and awareness and application of non-regulatory standards and codes of practice.  We consider that revising the NZ Packaging Council Code of Practice for Packaging Design, Education and Procurement and the APC to include information on the safety of chemical migration could be effective strategies in terms of Option 3. They have currency across the industry, they are widely used and there is an existing level of respect and familiarity with them. They are backed by both industry peak bodies and government alike. | NZ Food and Grocery Council | Noted. To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| MPI notes that P1034 identifies a lack of awareness from some food manufacturer’s businesses of risks of CMPF. Raising awareness with packaging suppliers, manufacturers, importers, and food manufacturers to consider the safety of CMPF is needed. This could be done under a program that is led and facilitated by expertise within FSANZ.  Agree that information and awareness programs could be targeted at the responsibilities of food businesses, particularly SMEs to use safe packaging materials and the regulatory requirements. It would also be helpful to provide more general information to consumers as there is both huge interest and confusion generated internationally. | NZMPI | Noted. |
| There is currently a lack of information addressing the re-use of packaging containers, such as bottles or water and containers used for take-away foods, by consumers.  Evidence-based research is required to inform consumers about the risk of CMPF from the extended re-use of these containers, and from using containers to reheat foods.  If re-use does constitute a risk, then consideration should be given to how to best inform consumers of the risk, for example, whether it should be mandatory to include this information on the packaging material or a label. | Queensland health | Noted.  FSANZ’s guidance material will also address issues specific to consumers. |
| In addition to the review and possible consolidation of the range of `industry standards’ identified by FSANZ, there needs to be a tool provided to enquirers (for example, consumers, SMEs) to assist in navigating through that information. For example: what does food grade mean? Can I microwave food in X?  FSANZ, the AFGC/NZFGC and packaging peak bodies are the most appropriate organisations to undertake this program.  There is a need when dealing with known risks to be able to respond rapidly to detections to remove product from the market. Option 3 would not provide this certainty for enforcement agencies. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources. | Noted.  See responses above relating to clarification of food grade.  FSANZ has in place an emerging and ongoing issues protocol in order to effectively manage new risks in the food supply. This also captures CMPF. |
| We believe that a non-regulatory approach involving an education/information program for industry participants with strong support from industry would be much less costly than a regulatory approach that includes a new regulatory scheme unique to Australia and New Zealand.  Trade associations, including SPI, offer regular conferences and webinars that address the latest issues in food packaging, and have many resources available to companies for continuing education. We would be happy to work with FSANZ to integrate information sessions such as these into an educational program.  The AFGC/NZFGC and packaging peak bodies are the most appropriate organizations to lead an education/information program for industry participants, and we would be glad to assist the Agency in its efforts in this regard | The Society of the Plastics Industry | Noted. |
| Peak bodies that should be involved in familiarising industry with any new provisions or raising awareness of CMPF?   * Packaging Council of Australia * Packaging Council of New Zealand * National Packaging Covenant Industry Association * Food and beverage industry associations | Scion | Noted. |
| In an information/ awareness program, the obligations for stakeholders should be presented along with record keeping requirements of manufacturers, supply chain traceability and encourage businesses to implement GMP. | Dupont | Noted |
| *Option 3: Non-regulatory options*  *3b: Industry self-regulation by industry standards or codes of practice*  *3c: Industry self-regulation by a co-regulatory approach* |  |  |
| Supported.  AFGC supports the Implementation Sub Committee for Food Regulation (ISFR) in conjunction with industry developing an industry best practice guideline to assist companies minimise chemical migration from packaging and demonstrate regulatory compliance.  Such a guideline can reference the various other standards that are currently in use and aid SMEs in navigating their role and responsibility.  This approach poses minimal cost to government and consumers and also provides a flexible document that can be readily updated as technologies, environments and best practice evolve.  Option 3c – Co-regulation  Not supported. The AFGC does not support the option of co-regulation. There is no evidence to suggest that industry self-regulation would be unable to address an issue in this space that could be solved by a co-regulatory model. Co-regulation would add unnecessary levels of administration and management structures, leading to additional costs for all parties involved. | AFGC | ISFR decided they did not have further information to add to a guide; however individual jurisdictions will provide relevant information and links to assist FSANZ in completing the guide. FSANZ will continue to work with industry to ensure the information is relevant and suitable as a general resource for a range of stakeholders, in particular SMEs.  The Guide will be made available through the FSANZ website. Noted. |
| This is a low cost but ineffectual approach; it will not provide adequate control over less responsible participants in the industry and will provide no clear choices to consumers in regard to product compliance. | Integrated Packaging | P1034 identified gaps in awareness and knowledge around CMPF and for this reason, FSANZ aims to develop a packaging information guide. The guide will assist Australian and New Zealand importers and food sellers ask the right questions when buying food packaging materials and food that is packaged overseas  In addition, the importer and food seller in Australia and New Zealand are required to ensure that the packaging used is fit for purpose and does not contaminate the food.  FSANZ’s information material will assist Australian and New Zealand importers and food sellers ask the right questions when buying food packaging materials and food that is packaged overseas. FSANZ notes that this approach would give all food businesses more access to the information they need to manage potentials risks from CMPF. |
| In relation to Option 3b, industry self-regulation by industry standards or codes of practice, there are already codes of practice in place which explains the very good uptake of non-regulatory measures including specific packaging industry standards and adherence to GMP. FSANZ lists nine standards/codes of practice that are available and which are used variously throughout the supply chain. Often a number of these work together for comprehensiveness or work within specific markets supplying packaging to or in the Australasian region.  In relation to Option 3c, industry self-regulation by a co-regulatory approach, New Zealand does not generally employ co-regulation and we therefore believe a combination of existing arrangements (Option 3b) and new arrangements (Option 3a and Option 4) are the preferred approaches to pursue. However, we acknowledge the Australian Packaging Covenant (APC) is a co-regulatory tool currently in use that may present as a mechanism for managing chemical migration. | NZ Food and Grocery Council | Noted. |
| Agree that these may provide an incentive for individuals and companies to develop and comply with self-regulatory arrangements in order to mitigate hazards from CMPF but that these should form part of a graduated approach option that will allow MLs to be considered when appropriate. | NZMPI | Noted |
| Nestlé supports Option 3C as the preferred approach. A Code of Practice would be a direction which would offer a degree of regulatory control, allow standards to be set and facilitate change with flexibility and efficiency. This would represent a system which would meet industry requirements in terms of setting the foundations for information sharing leading to the validation of safety. This would have the most impact with an acceptable cost to business. | Nestle | Noted. |
| Support the regulatory approach based on US FDA and EU legislation and we consider the non-regulatory option an instrument to support the application of regulatory measures. For example, the implementation of an accreditation system like Telarc, BRC and alike can help industries to reach a more structured and controlled system that facilitates the application of the legislation, especially for SMEs. | Sealed Air | Noted |
| *Option 4: Graduated approach* |  |  |
| Not supported.  The AFGC does not consider a graduated approach as the most appropriate response to the issue of chemical migration from packing into food.  Pursuit of Option 4 would require further rounds of consultation and the completion of a regulatory impact statement. Whilst the impact costs of such measures are always difficult to estimate, any introduction of limits within the Code will increase the testing requirements on companies. Due to the low levels of even the higher risk chemicals, testing would need to be highly sensitive and coupled with sophisticated sampling methods to ensure accurate results. This would add considerable expense to industry, which is likely to have a flow on effect to consumers. | AFGC | Noted but overall there was general support for a graduated approach.  Following application of the graduated risk management approach, FSANZ has not identified any chemicals that meet the criteria for a high risk chemical nor any evidence that the Code needs to be strengthened.    To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| Support option 4. | Integrated Packaging | Noted. |
| This approach is strongly supported by NZFGC.  The graduated approach will address not only chemicals with different risk profiles but also the concerns with clarity about current requirements and gaps in the awareness of chemical migration across the supply chain. The approach will capitalise on existing mitigation tools (codes of practice and related measures) whilst addressing the potential and prospective need that may be substantiated to more explicitly manage two chemicals, diethylhexyl phthalate (DEHP) and diisononyl phthalate (DINP).  These are chemicals that FSANZ has identified as potentially presenting a higher health risk and which may be best regulated in the same way as tin, vinyl chloride and acrylonitrile are regulated now.  Even if the work underway on DEHP and DINP does not support a need for regulatory measures to be developed for these chemicals, Option 4 provides the framework to address such chemicals in the future. In our view, Option 4 delivers a good balance between regulatory and non-regulatory approaches. When coupled with an education programme, this Option presents as a comprehensive but practical approach to the multiplicity of packaging chemicals in use today and into the future. | NZFGC | Noted. See response to AFGC submission. |
| The Code should continue to set limits for chemicals of concern to provide consumers with safety assurance and industry with regulatory certainty.  MPI believes that the Food Standards Code should continue to be the best place to set requirements for packaging materials. This includes adding any limits arising from the phthalate research. This provides consistency in both New Zealand and Australia for import and export of foods and packaging materials. | NZMPI | Noted. See response to AFGC submission. |
| The establishment of maximum limits for high risk chemicals is an integral part of Option 4, and the maximum limits for these packaging chemicals should be included in the Code. | Queensland Health | Noted See response to AFGC submission. |
| Support s option 4. MPI prefers Option 4 – the graduated approach as it covers the full range of risk based regulatory and non-regulatory options, including the use of guidelines. This allows maximum limits to be considered for high risk chemicals under the Australia New Zealand Food Standards Code (the Code). Other chemical risks can still be managed by regulation, if needed, under processing requirements. In New Zealand, for example, requirements may be made under the Animal Products Act 1999 or in regulations under the Food Act 2014. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources.  NZMPI  NSW Food Authority | Noted See response to AFGC submission. |
| We do not consider any specific chemicals need to be singling out in packaging regulation if the USA/EU regulations are used by companies. It would not involve any additional level of compliance for those operating to EU and USFDA standards. It would however usefully provide a level of clarity which currently does not exist with respect to SME / importers. | NCI Packaging  Packaging Council of New Zealand | Noted. |
| A benefit of the graduated approach is that it will provide high protection for the public by efficiently mitigating risk from CMPF without being too much of a burden to food businesses, packaging industry and raw material suppliers. In addition, this approach should provide more flexibility in regard to new and innovative packaging materials without compromising the safety of the public.  The idea of preparing a specific guideline for this approach is appropriate and should provide the much needed clarity and clear rules for industry. | Scion | Noted See response to AFGC submission. |
| Supports a graduated approach as proposed by FSANZ which addresses: chemicals with different risk profiles; concerns about clarity of current requirements as well as gaps in awareness. Believes that this approach, coupled with an education/awareness/information campaign, would lead to better overall management of CMPF. | Dairy Goat Co-operative (N.Z.) Ltd, (abbreviated as ‘DGC’). | Noted See response to AFGC submission. |
| Although the toxicity of certain phthalates, including di(2-ethylhexyl)phthalate (DEHP) and diisononyl phthalate (DINP), continues to be a topic of conversation among regulatory bodies, we are aware that both DEHP and DINP are safely used in certain food packaging applications without concern.  Specifically, we understand that DEHP and DINP are not expected to migrate to non-fatty foods. The limitations placed on the use of these substances in the EU, for example, indicate that no concern is noted when the substances are used as plasticizers in materials intended for repeated-use applications and/or materials intended to contact non-fatty foods. In addition, we understand that Australia’s National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has reviewed DINP and concluded that it may be safely used in toys and child care articles. In light of the safety concerns surrounding these substances, we would recommend adopting the current EU limitations on the use of DEHP and DINP.  We also want take this opportunity to note that, although the purpose of the document is not to comment on the 24th Australian Total Diet study (ATDS), it is important to highlight that some of the estimations are highly conservative. For example, the studies relied upon appear to be based on biomonitoring and other indirect methodologies, and we note that direct methods of estimating exposure to DINP and DEHP are more realistic and also lead to significantly lower estimates than do the estimates based on indirect methods. For these reasons, we encourage FSANZ to undertake a follow-up survey to more accurately estimate dietary exposures for use in assessing potential health and safety risks. | SPI | Noted. See response to AFGC submission. |
| Specific limits for DEHP and DINP for all foods similar to the limits set used for other packaging chemicals (tin, vinyl chloride and acrylonitrile).  Supports the setting of specific limits for DEHP and DINP, and has banned these Phthalates and all other Ortho- Phthalates from packaging. These phthalates are acceptable in very minor quantities only when used as a catalyst for polymerisation in plastic packaging. | Nestle | Noted See response to AFGC submission. |
| In regard to Specific limits for DEHP and DINP for all foods: This depends on the approach taken.  If other countries` regulations are being recognized in Australia and New Zealand, it needs to be checked that high risk substances such as DEHP and DINP are included in these regulations to ensure public safety.  If a non-regulatory approach is taken, the risk of substances such as DEHP and DINP to public health and safety needs to be highlighted and evidenced. Ways to mitigate this risk should be communicated to companies and consumers.  If a graduated approach is being taken and if the study that FSANZ is currently conducting on levels of DEHP and DINP found in a wider range of foods indicates that there is a risk to the public health and safety, then specific limits for DEHP and DINP should be included in the Code. This is a very effective way to ensuring that exposure to DEHP and DINP for consumers will be kept to a minimum. There are compliance costs to conform and label changes.  Benefits are potentially more sales and trust by consumers. | Scion | Noted See response to AFGC submission. |
| Before limits for DEHP and DINP in foods are considered there first needs to be greater characterisation of the risk. It is our understanding that fatty foods (such as milk products, fish or seafood, and oils) that are packaged in plastics that contain DEHP are more likely to have higher concentrations than other foods.  Other measures, such as limiting the use of DEHP-containing packaging to use for foods that primarily contain water, may be more effective to reduce exposure risk. | Dairy Goat Co-operative (N.Z.) Ltd, | Noted. See response to AFGC submission  FSANZ has further characterised the risk of DEHP and DINP in foods.  A targeted follow up survey of DEHP and DINP plus five additional plasticisers in Australian foods found that estimated dietary exposures are below the tolerable daily intakes (TDIs) for these substances and not of concern for human health. |
| Where it is determined that there is a potential risk, the departments would support the inclusion of MLs in the Code, in addition to risk mitigation measures in relation to each `risk’ chemical being provided in guidance.  Guidance material should be current, incorporate references to reputable international standards, consider the full range of food packaging materials and be relevant to the food. A Maximum Level (ML) would enable jurisdictions to take prompt action to remove foods posing a risk. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources. | Noted and see response to AFGC submission. To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| In supporting Option 4, the Food Authority considers that a guideline prepared by the Implementation Sub-Committee for Food Regulation (ISFR) for CMPF is the most appropriate management strategy.  Information prepared by FSANZ in Safe Food Australia (a Guide to the Food Safety Standards) concerning Standard 3.2.2 clause 9 Food Packaging would be useful in this guideline as it provides:   * a description of existing Food Standards Code requirements concerning food packaging materials. * identifies that the food industry is responsible for sourcing appropriate material for food packaging application. * provides appropriate resources that may be used by industry to demonstrate due diligence in regards to Chapter 3 obligations to ensure that food packaging material is fit for intended use (e.g. Australian Standard 2070:1999).   An ISFR guideline for CMPF would be publicly available to all stakeholders, therefore providing access to small-medium enterprises (SME’s). This would address the potential concern with resource availability to SME businesses identified in Proposal 1034. Jurisdictions, through their own networks could then promote the availability of this resource to SME businesses. | NSW Food Authority | ISFR decided they did not have further information to add to a guide; however individual jurisdictions will provide relevant information and links to assist FSANZ in completing the guide. FSANZ will continue to work with industry to ensure the information is relevant and suitable as a general resource for a range of stakeholders, in particular SMEs. |
| Information 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. *Comment: This needs to be divided into different types of packaging materials.*  Identifying where the responsibility lies for ensuring chemical migration risks are managed. *Comment: The responsibilities along the supply chain should be clarified (from raw material supplier to food business). To obtain a safe product all parties need to work together and share information.*  Steps industry might take to demonstrate compliance with the regulatory requirements. *Comment: Include compliance testing requirements for different types of packaging materials, types of food packaged and storage conditions. Maybe include examples of compliance certificates.*  Maybe there is a possibility to create a free hotline or advice bureau for questions in regard to food contact compliance for Australia and New Zealand.  There is the risk that including all industry standards and CoPs listed in the submission document will create more confusion than clarity. Some of these documents are quite generic and it is difficult to find answers to specific questions related to food contact compliance. If all industry standards and CoPs are going to be listed an indication should be given which types of packaging materials are applicable and what type of information is covered. | Scion | Noted.  It is not within FSANZ legislative remit to provide compliance advice including advice on compliance with regulatory requirements in Australia and New Zealand for food contact materials and packaging. FSANZ can provide general guidance only. |
| Our concern with this question is how a prescriptive approach could be achieved without being mandated?  We suggest that the prescriptive approach represents a sensible compromise, albeit an alternative to the suggested FSANZ graduated approach.  There is the specific additional benefit in a limited regulation if it addresses the unknown risk of food contact risk posed by SME/small importers. | NCI Packaging  Packaging Council of New Zealand | Following application of the graduated risk management approach, FSANZ has not identified a need for a prescriptive approach, and there were no chemicals that meet the criteria for a high risk chemical or evidence that the Code needed to be strengthened.    To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| Given the complexity of the subject, a regulatory approach can be preferred to ensure better compliance procedures. A guideline can be developed as technical document for implementation of the provisions mandated by the law. In this context, we consider a technical guideline as a valid instrument to support in particular the SMEs in applying the legislation.  We believe that the participation of industry to the development of guidelines would bring high value as it would integrate the business dimension into the regulatory requirements. However, we are of the opinion that existing industry standards should remain separated from any shared (gov.t + industry) guideline because they are often addressing very specific needs that are peculiar for restricted sectors. | Sealed Air | To improve awareness and knowledge about CMPF, FSANZ plans to develop a food packaging information guide. |
| NZFGC supports a guideline approach that would systematically cover the risk mitigation arrangements available and to raise awareness about risk mitigation options. While there may be a level of prescription involved (as suggested by the Australian Office of Best Practice Regulation), costs of a guideline could be are shared by industry and government in preparation (drafting, contributing to input, reviewing, circulating for comment etc) and in utilisation (industry in terms of uptake, ensuring familiarisation, training etc and government and industry on surveying uptake and compliance with guidance provisions).  NZFGC believes that an industry guideline should cover all mitigation options listed in Option 3b but primacy should be given to the NZ Packaging Council Code of Practice for Packaging Design, Education and Procurement (for New Zealand) and the APC (for Australia) if chemical migration matters can be included in these tools. This will provide for some level of consistency across the board but also flexibility for manufacturers where particular features of their business (technical, operational, business ownership and supply etc) may result in preferences for alternate mitigation measures to be employed. | NZ Food and Grocery Council | Noted.  FSANZ will consider a package of guidelines for inclusion in the information material. |
| MPI believes that priority could initially be given to guidance for food processors, food service and retail operators to inform them about packaging issues. In particular, how to confirm that the packaging they are purchasing is safe for the products they are producing.  The list of information on page 17 would be a useful start for inclusion in a guideline. Guidelines could be developed in conjunction with the Implementation Subcommittee for Food Regulation’s (ISFR). Discussion with jurisdictions and other stakeholders on the status, ownership, and development of a guideline would be beneficial. The identified information gaps should be noted and addressed by guidance and information materials particularly for small and medium enterprises (SMEs). | NZMPI | Noted. |
| The development of a guideline will lead to better awareness and implementation of measures to manage CMPF across industry and provide a valuable ‘go to’ resource.  All the industry standards and CoPs identified should be included in guidelines. It may be appropriate for some that do not include food safety measures per se to be provided as an additional resource or reference list. | Dairy Goat Co-operative (N.Z.) Ltd | Noted. |
| Only standards and Codes of Practice of relevance to the Australian and New Zealand context should be included. Care should be taken to ensure that contradictory or inconsistent information is not included in any guidance developed.  FSANZ’s following suggestions are appropriate:   * 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 * context should be included. | The Victorian Departments of Health and Human  Services and Economic Development, Jobs, Transport and Resources.  Nestle | Noted. |
| A degree of prescription may not be a negative issue, providing it does not hinder the process of change which is generally noted with regulation changes. Cost to industry would only be the labour involved in managing and implementing changes. Currently Nestlé devotes resources to managing safety and compliance so it would be envisaged that this would be sufficient with such a system.  The most appropriate guideline to address CMPF would be as follows:   * EU Regulations and FDA regulations as a base. In general the EU regulations have more rigger than the FDA. * The Swiss Ordinance for Printing Inks which links into the EuPIA. * The BFR for paper in contact with food.   Nestlé does not recommend the AS 2070 as this is now outdated and does not have the rigour seen in the EU and FDA standards. | Nestle | Noted. |
| We would be glad to work with FSANZ to develop guidance that is specifically tailored to the market in Australia and New Zealand. In our opinion, such a document should coincide with the regulatory frameworks in place in the U.S. and EU governing food-contact materials.  To streamline the manner in which food packaging materials would be regulated under any potential non-binding guidance, we would recommend including all the industry standards and CoPs identified in option 3b (under the non-regulatory approach) in the guidance. This approach would allow the guidance document to serve as a single, comprehensive resource for industry and would avoid any potential oversights by industry in understanding the key regulatory considerations applicable to their businesses. | SPI | Noted. |
| Ongoing monitoring and surveillance | **Raised by** | **FSANZ response** |
| Post market surveillance is necessary to determine the success, or otherwise, of any intervention of this nature. The AFGC recommends that FSANZ add phthalates to the regular cycle of the Australian and New Zealand Total Diet Studies to track exposure over time and assess whether the outcomes of P1034 have served to reduce chemical migration from packaging into food. | AFGC | Noted.  A targeted follow up survey of DEHP and DINP plus five additional plasticisers in Australian foods found that estimated dietary exposures are below the tolerable daily intakes (TDIs) for these substances and not of concern for human health.  FSANZ will also continue to monitor CMPF issues as they emerge and will consider appropriate management options if required. This will include phthalates. |
| Monitoring and surveillance strategy is not effective to enforce the existing guidelines for all manufactured or imported film due to the range and quantum of packaging materials and suppliers. This would require the revision of the Food Act to encompass importers and manufacturers of food contact packaging. | Integrated packaging | Revision of the Food Acts is outside of FSANZ’s remit and the scope of this proposal. Amendment or otherwise of the Food Acts are a matter for Governments. |
| NZFGC believes that gathering evidence of ‘unknown’ risks associated with chemical migration from packaging into food through a monitoring and surveillance strategy is appropriate for gathering data from the food supply in Australia and New Zealand which in turn is important for evidence-based standards setting. Such a strategy that incorporates monitoring international research developments and reports, is a practical response that NZFGC supports. | NZ Food and Grocery Council | Noted. |
| MPI agrees that future surveys could be considered under the ISFR Coordinated Food Survey Plan. | NZMPI | Noted. |
| Clorox is supportive of an ongoing monitoring and surveillance strategy, by enforcement and  compliance of food laws to identify and manage unknown risks associated with CMPF.  Clorox believes that the data obtained from the monitoring and surveillance should be carried out  for a couple of years to establish a robust baseline data for CMPF (like phthalates).    Decision for a prescriptive approach option should only be made after the CMPF baseline data on phthalates  indicated that the dietary exposure limit is attributed solely from plastic food contact material and that it presented a health risk to the consumer.  Clorox believes that establishing a robust baseline data for CMPF (e.g phthalates) attributed to plastic food contact material is important as our experiences had shown that test data can easily be skewed easily by other contaminants in the environment as well as other factors. | The Clorox Company | Noted. |
| In principle, we are satisfied that the ongoing regime of the Australian total diet study (ATDS) provides acceptable monitoring through agreed protocols and testing regimes.  However we do have some concerns:   * Testing for unknown or speculative risks can require unwarranted testing protocols and regimes. Risks which are rational are already addressed under current testing regimes. “ * Food contact” is not defined. This affects both those wishing to provide assurance, and those seeking to rely on testing to provide assurance. * How is it established that the source of contamination is in fact the packaging and not the product, given the risk is a function of total exposure and contact packaging is by no means the only risk pathway. Note, migration testing is undertaken with food stimulants for this reason | NCI Packaging  Packaging Council of New Zealand | Noted. |
| We consider an ongoing monitoring as a preventive tool to control the unknown risk associated with food packaging of uncertain cost/benefit results and without guaranteed advantage for risk mitigation. Moreover, the variety of materials and products on the market would require the development of an excessive number of analytical techniques. A more effective approach would be the implementation of a governmental structure that could be activated in case of alarms related to contaminants of toxicological concern for the consumer. | Sealed Air | FSANZ has in place an emerging and ongoing issues protocol in order to effectively manage new risks in the food supply. This also captures CMPF. |
| Suggested that additional health and safety protection might be gained by the adoption of a system of compliance of food-contact materials with the requirements in place in the U.S. or the EU. The added protection that will come with the adoption of such a system would come at little cost to FSANZ to develop, as the U.S. and EU systems are comprehensive and could be easily cross-referenced in the Code. Moreover, as most packaging material is developed to meet the standards in the U.S. and the EU, there would be little disruption in the market, but a higher level of safety is ensured. | Society of the Plastics Industry | FSANZ’s risk assessment showed that there was insufficient evidence indicating that the Code needs to be strengthened through adoption of other countries regulations. However, international regulations will be covered in the packaging information guide to be developed. |
| An ongoing monitoring and surveillance strategy led for example by “the Implementation Sub-Committee for Food Regulation” (ISFR) could be a practical measure to identify and manage risks associated with CMPF.  However the usefulness of such a measure will be  determined by the format of the surveying program that is going to be used (e.g. frequency of surveying, type of packaging material and supply chains chosen for surveying and type of test methods used). A monitoring program might also raise further awareness for food companies and highlight their accountability to ensure that the packaging they are using is safe. | Scion | Noted. |
| The focus for identifying new potential risks should be on-going monitoring of developments.  Surveillance is of limited use in managing unknown risks unless there is good intelligence regarding potential new risks to guide this work.  MPI is recommended to be the peak body utilised in New Zealand.  The Food Safety Centre established at Massey University in New Zealand could potentially be used to undertake surveillance activities within New Zealand. | Dairy Goat Co-operative (N.Z.) Ltd. | Noted.  FSANZ has in place an emerging and ongoing issues protocol in order to effectively manage new risks in the food supply. This also captures CMPF. |
| Support ongoing monitoring and surveillance strategy.  This should be considered as part of a revised system of control of which monitoring is only one part. The AFGC is an appropriate peak body which should be involved in familiarising industry with any new provisions or raising awareness of CMPF. | Nestle | Noted. |
| Ongoing monitoring and surveillance strategies should be conducted by FSANZ using risk-based assessment approaches. This, along with targeted education and awareness efforts, would complement any regulatory approach and assist to address the risks in the current framework posed by stakeholders with knowledge and regulatory awareness knowledge gaps. | Dupont | Noted |
| Ongoing analytical surveys investigating the presence of specific packaging chemicals in Australian foods should be conducted as a “watching brief” to monitor new developments in packaging materials. This surveillance work could be incorporated in future Australian Total Diet Surveys (ATDS), as was done in the 24th ATDS which incorporated chemicals from packaging.  The establishment of a central co-ordination agency for receiving complaints and enquires relating to CMPF would also be a mechanism for capturing emerging issues. | Queensland Health | Noted |
| Ongoing monitoring and surveillance at a national level continues to be a practical measure to assist in the identification of unknown risks associated with CMPF.  The Australian Total Diet Surveys, informed by emerging issues, are the appropriate vehicle for this work. Jurisdictions do not have the expertise or resources to undertake this type of work. It is critical that FSANZ is adequately funded to maintain the expertise and resources required to perform monitoring and surveillance activities of national significance. | The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. | Noted. |
| Costs and benefits | **Raised by** | **FSANZ response** |
| Could represent a cost to those companies who currently do not meet USFDA and/or EU standards.  However consumers are entitled to assume products are safe. Those not meeting defined EU / USFDA standards may or may not be putting consumers at risk but should accept the costs of such assurance as a reasonable expectation of consumers and the community. | NCI Packaging  Packaging Council of New Zealand | Noted. |
| Our preferred option is 4: a graduated approach, subject to comments raised above. This is proportionate to the risk and provides for minimal effective regulation. However, this relies on FSANZ, jurisdictions and industry working together to provide assurances that the graduated approach is effective in managing the risks associated with CMPF.  Further information on proportion and manufacture of imported packaging may be useful to provide assurance that the proposed approach will manage risks comprehensively. For example, does FSANZ know what proportion of packaging is being sourced directly from overseas sources and what processes food businesses have in place to determine the safety and suitability of these packaging products? | The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. | Noted |
| Welcomes changes which assist in the Safety and compliance of CMPF. Currently Nestle has an in-depth program which complements all proposals without any foreseeable additional costs. | Nestle | Noted. |