



December 23, 2014

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Via Electronic Mail

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia

Re: Proposal P1034 - Chemical Migration from Packaging into Food

Dear Sir or Madam:

The Society of the Plastics Industry, Inc., (SPI) by its attorneys and through its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), hereby respectfully submits comments to Food Standards Australia New Zealand (FSANZ) on Proposal P1034 on chemical migration from packaging into food.^{1,2} We appreciate the opportunity to comment on the proposal to assess whether there are any unmanaged public health and safety risks relating to chemical migration from packaging into food, and if any such issues are identified, to assist FSANZ with determining how those risks can be managed.

I. FDCPMC Background

The FDCPMC is composed of SPI members with particular interest and expertise in packaging for food, drugs, cosmetics, and related products. SPI created the Committee to

¹ The proposal and supporting documentation are available at <http://www.foodstandards.gov.au/code/proposals/Pages/P1034ChemicalMigrationfromPackagingintoFood.aspx>.

² Founded in 1937, The Society of the Plastics Industry, Inc., is the trade association representing one of the largest manufacturing industries in the United States. SPI's members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The U.S. plastics industry employs nearly 900,000 workers and provides more than \$373 billion in annual shipments, both foreign and domestic. U.S. plastics manufacturers export food packaging materials worldwide, including Australia and New Zealand, and have a strong interest in ensuring that all materials used in contact with food are safe and suitable for their intended use.



support government agencies working on food packaging regulations, and to assist members in their understanding of, and compliance with food packaging regulations. The Committee has worked cooperatively with government agencies worldwide on regulatory issues relating to packaging since its formation in 1957. For over 50 years, the FDCPMC has worked closely with the U.S. Food and Drug Administration and the European Food Safety Authority (EFSA), and more recently with Health Canada, the Japanese National Institute of Health Sciences (NIHS), the Chinese National Center for Food Safety Risk Assessment (CFSA) and the Chinese National Health and Family Planning Commission (NHFPC), as they have worked to develop and improve the regulatory framework governing food-contact materials in their respective jurisdictions.

With respect to food safety and food packaging, the Committee's cooperative efforts with regulatory agencies focus on the shared goal of developing regulations that ensure protection of the public health while promoting market access for safe and suitable food packaging materials worldwide. The Committee has provided survey data on the use of specific plastics, conducted research, and provided practical advice on the functioning of the industry and effective product stewardship programs. We want to take this opportunity to express our interest and willingness in being a resource for FSANZ as the agency continues to evaluate the current regulatory scheme for food packaging in Australia and New Zealand, and would welcome further collaboration with FSANZ and other agencies that regulate food packaging materials as the current consultation proceeds.

II. FSANZ Consultation

We understand that the current consultation paper requests information that will increase FSANZ's understanding of how food packaging is used in food production and the possible risks from chemical migration from packaging into food. FSANZ will then use that information in its evaluation of Proposal P1034 to determine whether current risk mitigation measures are sufficient to address any risks. Currently, the law in Australia and New Zealand requires that packaging must be safe and suitable for its intended use. We believe that this safety standard, which is very similar to the underlying standards for food packaging regulatory schemes worldwide, has been more than sufficient to ensure that materials contacting food consumed in Australia and New Zealand have not caused any public health or safety concerns, and would continue to do so without any legal or regulatory revisions. Our position on the sufficiency of the current regulatory scheme is supported in more detail, below. However, if FSANZ does consider it necessary to implement more stringent measures, we recommend that it should be mandatory for any food contact material or article used in Australia or New Zealand to comply with the laws and regulations administered by the U.S. Food and Drug Administration or in place within the European Union.³ The FDA and EU regulatory systems are comprehensive, accepted

³ We are not proposing to require that all materials must have specific premarket approval by FDA, but rather that the materials must have a suitable FDA status for their intended use.

in global commerce, and keep pace with packaging innovation, while protecting public health. Relying on these existing systems would ensure that materials, both virgin and recycled, have been subject to rigorous premarket review, without imposing new any new and potentially resource-intensive procedural requirements on either industry or FSANZ.

III. Purpose of Food Packaging

Packaging is an essential component in ensuring the safety and quality of food. The substances and materials used to produce packaging are selected to have technical properties that preserve the quality of the food, prevent nutrient and flavor scalping, extend the shelf-life of products, and prevent intentional or accidental adulteration of food. Packaging is also essential for the reduction of food waste, with significant economic, public health, and environmental benefits. Manufacturers continue to innovate, producing ever-safer products with less impact on resource consumption and the environment.

Because packaging plays a major role in food safety, manufacturers of food packaging materials recognize the imperative to ensure their products are safe and meet regulatory requirements. For this reason, companies design and manufacture their products to *prevent* the transfer of substances in the packaging to food, and in this way ensure that the food packaging materials will serve their intended role in protecting food from spoilage and tampering, and minimizing waste. The food packaging industry recognizes that it is not desirable to produce packaging from which substances could migrate at high levels (unless intended for purposes of preserving the quality of the food), as this could cause off-flavors or odors in the food which could, in turn, make the food unmarketable. The potential remains, nevertheless, for substances to migrate from food packaging to food. Given this situation, the question is not simply whether such transfer occurs, but also whether migration results in a substance being present in the diet at a level that is safe; the mere presence of a chemical substance in food resulting from migration from packaging does not automatically result in a health or safety concern.

IV. Food Packaging and Food Safety⁴

As an overarching matter, we consider food packaging to present a very low risk to the safety of food, a fact that is born out in the consultation paper. In this paper, FSANZ could identify only two or three specific incidences over many years of substances migrating from packaging where safety concerns have been expressed; even for those particular examples, there was no conclusion that the migration presented a risk significant enough to warrant further

This will prevent the imposition of new and unnecessary burdens on companies, particularly small businesses, who may be marketing their products based on an exemption provided in FDA law and regulations from the need for specific approval by the Agency.

⁴ This section addresses Questions 1, 4, and 5 of the response template.

restrictions on use.⁵ Moreover, food companies and food packaging manufacturers have invested substantial resources to produce packaging materials that are safe for use in contact with food, thereby ensuring the continued protection and success of their brand name products.

As in every regulated industry, there is a continuing need for education to ensure that food packaging manufacturers understand the regulations and are using the most current science and risk assessment techniques to establish the safety and suitability of their products. While many manufacturers are highly sophisticated in this area, food packaging is a global industry and there are opportunities for large companies, together with smaller manufacturers, to share knowledge and expertise that will help all members of this industry ensure product compliance and use of good manufacturing practices. Risk assessment and risk management methodologies are constantly evolving, and it is important for packaging manufacturers to be aware of the latest regulatory and scientific developments. Trade associations, such as SPI and its counterpart PlasticsEurope, offer regular conferences and webinars that address the latest issues in food packaging, and have many resources available to companies for continuing education.

V. Regulatory Framework for Food Packaging⁶

FSANZ develops and maintains food standards for food and food packaging products, which are binding legislation, published as the Joint Australia New Zealand Food Standards Code. Regulatory enforcement of the Code is covered by the general Australian state and territory Food Acts and New Zealand Food Act. Standard 1.4.3 of the Code addresses Articles and Materials in Contact with Food, but does not establish any specific compositional requirements or premarket approval process for food packaging.⁷ More importantly, the Standard includes an editorial note stating that it is the responsibility of food manufacturers and retailers to ensure that their products, and by extension, the materials and articles packaging their food products, are safe. Manufacturers consider this Standard, with the editorial note, to generally impose an affirmative obligation to ensure that food packaging materials are safe and suitable for their intended use. As you know, the editorial note to Standard 1.4.3 also contains a reference to a nonbinding standard for plastic materials for food-contact use – Australian Standard (AS) 2070-1999, which is administered by Standards Australia, a non-governmental

⁵ We are not including the discussion on bisphenol-A (BPA) as a specific incidence because both the U.S. Food and Drug Administration and European Food Safety Authority, the two most well-established food packaging regulatory agencies in the world, have continued to maintain that current levels of dietary exposure to BPA are safe.

⁶ This section responds to Questions 1, 2, 9, 10, and 12.

⁷ We understand that a proposal, P1025, to revise the Code's structure and format is currently active. As this has not yet been finalized, we continue to refer to the Standards provided in the currently effective Code.

organization.⁸ AS 2070-1999 is not part of the Code and is not binding; it is, nevertheless, widely followed in Australia. The standard explicitly states that new plastic materials must comply with the food contact regulations for plastics in the United States or Europe.⁹ The standard also looks to U.S. and/or EU regulations for processing aids, additives, colorants, and coatings. Clearly, Standards Australia considers the food contact regulations in those two jurisdictions to be appropriate for establishing the safety and suitability of a food packaging material. Because AS 2070-1999 is widely followed, we consider that a continuation of this regulatory scheme by FSANZ, albeit non-binding, would have no adverse impact on the safety of packaging materials and food in Australia and New Zealand.

Recognizing, however, that there is likely to be significant pressure on FSANZ to take specific actions to bolster the regulatory framework for food packaging, we would recommend that in any such action FSANZ simply mandate that any plastic material or article used to package food sold in Australia or New Zealand should comply with the laws and regulations administered by the U.S. Food and Drug Administration or in place within the European Union. This would ensure that both new and recycled plastics are subject to rigorous premarket regulatory schemes that are recognized worldwide for ensuring that food packaging materials are safe and suitable. By formally recognizing the U.S. and EU regulatory systems as the basis for demonstrating safety, there will be significant benefits to industry, consumers, and to FSANZ. The primary benefit to consumers and industry would be the use of simple, predictable, and established methods for demonstrating the safety of food packaging products. This would also avoid the unnecessary duplication of efforts by both industry and FSANZ to regulate materials that have already been determined to be safe by internationally recognized regulatory agencies, freeing FSANZ to focus its resources on areas involving more significant concerns for public health and global commerce. Both the U.S. and EU programs are based on scientific rigor and application of an evidence-based approach in the way they conduct their safety reviews for food contact substances, and can be relied upon to support the safety of food packaging used in Australia and New Zealand.

⁸ These Australian Standards are prepared by Technical Committees comprised of stakeholders.

⁹ Paragraph 4.1.1.



We appreciate the opportunity to submit comments on Proposal P1034, and trust that FSANZ will continue to engage stakeholders in the consultation process. If you should have any questions regarding our comments, or if we can provide you with any additional information regarding the regulation of food packaging materials in the U.S. or EU, or even in other jurisdictions, please do not hesitate to contact us.

Sincerely yours,



Senior Director, Global Regulatory Affairs
Society of the Plastics Industry, Inc.

