

# Nano-Food Packaging: An Overview of Market, Migration Research, and Safety Regulations

Nattinee Bumbudsanpharoke and Seonghyuk Ko

**Abstract:** Recently, food packages produced with nanoparticles, “nano-food packaging,” have become more available in the current market. However, although the use of nanomaterials is increasing in food packaging applications, concern over toxicity affects consumer perceptions and acceptance. Quite a number of commercialized forms of nano-food packaging are coated or composited product with inorganic materials, for example, nanosilver and nanoclay as representative examples. Several studies have shown the possibility of nanomaterial migration from packaging or containers to foodstuff. The debate is still ongoing among researchers about the extent of migration and whether it is negligible and safe. Government agencies and stakeholders must hurry to determine use limitations and release conclusive legislation and regulations as soon as possible since nano-food packaging may have great impacts on human health. This paper aims to review the availability of nano-food packaging in the current market, report case studies on nanomaterial migration, and present the current status of safety regulations and management of nano-food packaging in leading countries across regions. This review should enable governments and researchers to develop further nanomaterial risk assessment studies.

**Keywords:** Food packaging, nanoparticles, risk assessment, safety, migration

## Introduction

Over the past decade, the emergence of new technologies based on nanomaterials has created great excitement and enormous interest. According to the Cosmetic Regulation (EC No 1223/2009), a nanomaterial is defined as an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on a scale from 1 to 100 nm (European Commission 2009c). Nanomaterials can be polymeric materials, composite materials, metals, or ceramic (Venugopal and Ramakrishna 2005). New properties and functions of nanoscaled particles present new opportunities to enhance traditional product performance; thus, they have been considered as alternative novel materials across a wide range of industrial, pharmaceutical and biomedical fields, structural and construction materials, information technology, and electronic applications (Landsiedel and others 2010; Lue 2007). Ordinary material properties can be improved in terms of durability, flame resistance, barrier properties, flexibility, or recycling properties (Chaudhry and others 2008; Markarian 2005). Thanks to their unique multifunctionality, a wide spectrum of nanomaterials is in use for consumer products and various new products containing nanomaterials have been launched in the market.

The food and beverage industry has been a recent focus for nanomaterial applications. Even though it is a newly emerging technology, it is predicted to continually increase (Blasco and Pico 2011). It is estimated that up to 400 companies around the world are developing possible applications of nanotechnology in food and food packaging (Neethirajan and Jayas 2011). According to Persistence Market Research report titled “Global Market Study on Nano-Enabled Packaging For Food and Beverages: Intelligent Packaging to Witness Highest Growth by 2020,” the global nano-enabled packaging market for food and beverages was estimated to be \$6.5 billion in 2013 and will grow at a compound annual

growth rate (CAGR) of 12.7% to reach about \$15.0 billion in 2020 (CNBC 2014; Persistence Market Research 2014). On the other hand, the European Institute for Health and Consumer Protection revealed that the use of nanomaterials in the food packaging market is expected to reach \$20 billion by 2020 (the entire nanotech industry is expected to reach \$1 trillion by 2015) (Belli 2012).

Nanomaterials in foods can be naturally produced as well as intentionally added by man-made materials. Intentionally added nanomaterials may come from two sources; naturally occurring or engineered material sources, which are not generally present in a food substance (Magnuson and others 2011). Animals and plants can produce nanoscale components, for instance, casein micelles in milk (Tuinier and de Kruif 2002; Aguilera 2014) show dimensions of 300 to 400 nm and pectin nanostructures in fruit (Zhang and others 2008) show polymer chain length about 100 to 400 nm. On the other hand, there are many engineered nanomaterials in development for the food industry because of the expected benefits. For example, nanometer grains of salt have been developed to reduce salt consumption by increasing its surface area, and as a result, a small amount of nano-salt can give human taste buds the same original savory taste (Rasouli and Zhang 2006). Moreover, one of the main benefits of nanomaterials is as a carrier for vitamins or minerals through encapsulation. Nanomaterials are being used to deliver nutrients in food, beverages, and supplements without affecting its taste or appearance. Nanocapsules carry vitamins through the human stomach via the bloodstream (Thies 2012). However, there is a possibility that unintentional nanomaterial contamination of food can occur via migration from food contact packaging or from pesticides (Magnuson and others 2011).

Nanotechnology provides a new lightweight material with stronger packaging barriers, which protect food quality during transportation, prolong fruits and vegetable freshness during storage, and preserve meats or poultry from pathogens. Currently, nanomaterials have been applied to several kinds of food contact packaging and container since they represent a new alternative additive source for improving polymeric properties of packaging materials. For instance, barrier properties, mechanical properties,

*MS 20141952 Submitted 11/27/2014, Accepted 3/4/2015. Authors Nattinee Bumbudsanpharoke and Seonghyuk Ko are with Department of Packaging, Yonsei University, Seoul, South Korea. Direct enquiries to author Ko (Email: s.ko@yonsei.ac.kr).*

and heat resistance properties can be enhanced with the use of certain nanomaterials.

Improvement in barrier and mechanical properties can be achieved by polymer blending according to conventional methods. However, this often requires complex multilayer films or blending polymers which have high production and material costs and requires additional additives and adhesives for binding, which is time consuming. In addition, this may generate complexities in the recycling process (Duncan 2011). Therefore, a monolayer film with a biocompatible material such as nanoclay is even more efficient in regard to manufacturing, cost, and recycling if the final properties are similar. In the 1990s, nanocomposites for food packaging began using montmorillonite minerals as nanoclays with nylon, polyethylene (PE), polyvinyl chloride (PVC), and starch (Brody and others 2008). A classic example of the use of nanoclay is to improve the mechanical and barrier properties of plastic packaging (Arora and Padua 2010).

However, as the material dimensions are on a nanometer scale, it is presumed that this may change or influence the physical, chemical, and biological aspects of the adjacent environment, including the human organism (Landsiedel and others 2010; Oberdorster and others 2005). The greater chemical reactivity and bioavailability of nanomaterials may also result in greater toxicity of nanoparticles compared with the same unit of mass of larger particles of the same chemical composition (Hoet and others 2004; Oberdorster and others 2005). It is known that materials that are 300 nm or less in diameter can be taken up by individual cells (Garnett and Kallinteri 2006), and nanomaterials which measure less than 70 nm can even be taken up by a cell's nuclei, where they can cause major damage (Chen and von Mikecz 2005; Geiser and others 2005). Nevertheless, it remains unknown what levels of nano-exposure we are currently facing, what levels of exposure could harm human health or the environment, if there is any safe level of nano-exposure, and whether or not nanomaterials will bioaccumulate along the food chain. Therefore, until we have a more comprehensive understanding of the biological behavior of nanomaterials, the regulation and limitation of nanomaterial applications in food contact materials must be clarified.

This review will focus on the available research from literature and internet references on the migration of inorganic nanomaterials from food packaging and the status of legislation from national governments. The recent development of commercialized food packaging with nanomaterials and the risk perception of nanomaterials by the public will be discussed as well.

## Types and Functions of Nanomaterials in Food Packaging

Currently, a variety of engineered nanomaterials have been introduced to food packaging as functional additives including silver nanoparticle (AgNP), nanoclay, nano-zinc oxide (nano-ZnO), nano-titanium dioxide (nano-TiO<sub>2</sub>), and titanium nitride nanoparticle (nano-TiN) (Mohanty and others 2009; Tager 2014). Due to differences in chemical structure and characteristics, each nanomaterial introduces distinct properties to the host material, which lead to different functional packaging applications (Rubilar and others 2014). AgNPs are metallic silver atom clusters that are engineered mostly for antimicrobial and sterilization purposes. Because AgNP has a larger surface area per mass than micro-scale silver particles or bulk silver material, the potential to release silver ions is also greater than that of bulk silver (Marambio-Jones and Hoek 2010). Nanoclays, layered silicates, are naturally occurring fine-grained minerals (Majeed and others 2013). The dispersal

of sheet-structured nanoclay into the polymer matrix creates the enhanced barrier properties of homogeneous polymer due to the increase of tortuous pathway against penetrating molecules (Duncan 2011). Metal oxide nanoparticles such as zinc oxide and titanium dioxide are often used as photocatalysis agent to degrade organic molecules and microorganisms. The photocatalytic reaction of nano-ZnO and nano-TiO<sub>2</sub> attributes to generation of reactive oxygen species (ROS), resulting in the oxidation of cytoplasm of bacterial cells and leading to cell death (Bodaghi and others 2013). It was reported that ZnO is relatively more efficient and attractive over silver due to the less toxicity and cost effectiveness (Duncan 2011; Silvestre and others 2011). Nano-TiN, an approved food contact material by European Food Safety Authority (EFSA) (EFSA 2012), is generally synthesized by heating TiO<sub>2</sub> particles in a nitrogen-containing gas at high temperature (Dong and others 2011). Nano-TiN is widely used for mechanical strength and processing aid particularly for polyethylene terephthalate (PET) (Chaudhry and Castle 2011). The next section will outline the current nano-food packaging products using aforementioned inorganic nanomaterials.

## Current Commercialized Nano-Food Packaging in the Market

Nanocor, a subsidiary of Illinois-based AMCOL International, is the one major global supplier of nanoclays specifically designed for plastic nanocomposites and has commercialized nanoclay-based resins and packaging products developed with the montmorillonite minerals. For example, Durethan<sup>®</sup> KU2-2601, a combination of engineered plastic polyamide 6 (nylon 6) and nanoclay, is a transparent composite for the barrier film and coating in packaging. Durethan<sup>®</sup> can be applied in various areas of packaging, from ordinary foodstuff to the medical field since the clay nanoparticles are dispersed throughout in a polymer matrix, providing excellent properties of gas and moisture barrier, strength, toughness, and abrasion and chemical resistance (Sekhon 2010; Chun 2009; Duran and Marcato 2013; Zeng and others 2005; Cushen and others 2012). This product is now available from Lanxess Deutschland GmbH (Hatzigrigoriou and Paspapyrides 2011).

Aegis<sup>™</sup> OXCE is nylon 6-nanoclay composite that was developed by Honeywell Polymer (Honeywell International Inc 2013). Unlike Nanocor's products, it is modified with additional oxygen scavenger and is used in high-oxygen barrier packaging for beer and flavored alcoholic beverage. It was already commercially successful with the 1.6-L Hite Pitcher beer bottle from Hite Brewery Co. in South Korea (Cooper 2013; Peters and others 2011; Picó and Blasco 2012) Imperm<sup>®</sup>, nylon nanocomposites, was developed by using MXD6 (nylon polymer from Mitsubishi Gas Chemical Company, Inc.) in conjunction with Nanocor and Voridian; a division of Eastman Chemical. This nano-composite is applicable in a barrier layer for thermoformed containers or a multi-layer PET bottle which can be used for beer, liquor, or small carbonated soft-drink beverages (Amico 2004; Nanocor 2008). It is currently commercialized by Miller Brewing (U.S.A.) in their plastic beer bottles; particularly in Miller Lite, Miller Genuine Draft, and Ice House brands (Chaudhry and others 2008). Recently, Imperm<sup>®</sup> is globally supplied through ColorMatrix Group. PolyOne Corp developed Nanoblend<sup>™</sup> with 40% nanoclays in homo- and modified polypropylene (PP), linear low-density polyethylene (LLDPE), low-density polyethylene (LDPE), high-density polyethylene (HDPE), or an ethylene copolymer matrix. They brought alternatives to market for polyolefin based-nanoclay composite (Amico 2004). This polyolefin based nanocomposite

provides a superior oxygen and water barrier, but higher haze and lower clarity than nylon based composited (Qian and others 2009). In addition to nylon-based nanoclay composite products, Plantic Technologies Ltd. developed thermoformed starch-based nanoclay composite and market with name of Plantic<sup>®</sup> R1 Tray (Khemani and others 2008). This tray is used in Cadbury<sup>®</sup> Dairy Milk<sup>™</sup> and Milk Tray<sup>™</sup> chocolates and Marks & Spencer Swiss chocolates (Plantic Technologies Limited 2007).

Nanosilver is typically used for antimicrobial effect. Around 650 disease-causing pathogens can be killed by silver molecules with only 6 min of contact time, whereas general antibiotic kills only 5 to 6 disease-causing pathogens (Han and Li 2008; Thanh and Phong 2008). Nanosilvers are applied to food packaging or containers to promote their antimicrobial properties and a large number of antibacterial food packaging products using nanosilver are readily available on the market around the world. Electronic commerce, a new generation of goods distribution route, is a convenient channel to search and purchase antimicrobial food containers. Branded and unbranded products from different sources and countries are easily found on online market. Several examples are listed in Table 1; e.Window<sup>®</sup> nanosilver food containers, Dokdo Anti-Bacterial Food Storage Container, Everin<sup>®</sup> Food Containers Nano Silver Airtight, and FresherLonger<sup>™</sup> Miracle Food Storage and Plastic Bag. These products claim that nanosilver helps to effectively reduce the growth of bacteria and keep product fresh longer.

Baby Dream Co., Ltd., an infant product company in South Korea, has developed a baby mug and milk bottle with AgNPs. The company started a large scale operation with Seoul National University Hospital, followed by discount markets and big distributors in Korea with the claim that this container maintains 99.9% germ suppression, deodorization, and freshness even without sterilization (Momin and others 2012). In China, Quan Zhou Hu Zheng Nano Technology Co., Ltd. launched Baoxianhe Nanosilver Storage Box and Anson Nano-Biotechnology (Zhuhai) Co., Ltd. began nanopackaging marketing with Anson Nano Antimicrobial Storage Series; plastic bags and film for fresh food. In Taiwan, nano-zinc oxide is used by SongSing Nano Technology Co., Ltd., for anti-mold plastic wrap. It claims to sterilize completely under indoor light conditions.

Furthermore, nanomaterials can be used in food packaging for various functions, not only as a barrier or antimicrobial agent. EcoSynthetix, a global bio-based material company, has developed a new technology, called EcoSphere Biolatex<sup>®</sup> (EcoSynthetix 2014). Their research involves producing a natural base binder from annually renewable resources such as corn or potato starch by modifying the starch molecule. The new biopolymer nanosphere has a high solid dispersion in water; its granule size is just 50 to 150 nanometers. This is a 400-times higher surface area than a natural starch granule, and therefore, EcoSphere Biolatex<sup>®</sup>'s performance is better than traditional starch and on par with polyvinyl acetate (PVA) adhesive (Klass 2007). This nanostarch has been used for McDonald's hamburger clamshells in the United States, replacing traditional adhesive (Blasco and Pico 2011). In addition, TiN is another kind of nanomaterial which is added to plastic for processing purposes. It is mixed with plastics, particularly PET, because it can improve the thermal properties of the material and allows for an increase in the production output of PET bottles (EFSA 2012). A nanosensor is a type of nanotechnology application by spraying a CNTs thin film on a label or surface of smart packaging. CNTs-based gas sensors show an exceptionally high performance as well as immediate response to the ammonia (NH<sub>3</sub>) and carbon

dioxide (CO<sub>2</sub>) gas (Abdelhalim and others 2013; Abdellah and others 2013). Food packaging enables detection, sensing, and communication and can alert shopkeepers if their meat products are at risk of spoilage. This sensor in a form of a sprayed carbon nanotube onto a clear film is an emerging technology (Meyer 2013). Table 1 shows examples of nano-food packagings currently available in market.

## Recent Studies on Nanomaterial Migration in Food Contact

An adequate toxicological data is not yet available and safety assessments are still in progress. Over the last few years, several studies have reported the migration of nanoparticles into foodstuffs. Most of these studies have focused on nanosilver as there are concerns by the public and government about its safety and health effects. Some reports have indicated that nanosilver may harm human cells by modifying the function of mitochondria, increasing membrane permeability, and generating reactive oxygen species (Song and others 2011). Song and others (2011) studied the migration of nanosilver from PE packaging with food simulants by inductively coupled plasma mass spectrometry (ICP-MS) determination, and the results showed that the amount of migration of silver slightly increased with time and temperature in 3% (w/v) acetic acid prior reaching a steady state. However, in 95% (v/v) ethanol, the amount of nanosilver migration depended on time, while temperature did not show any significant effect. Within this test limitation, they suggested that further migration studies of nanoparticles need to be performed with real food samples, as silver nanoparticles are not likely to be used in high acid foods.

In China, the National Packaging Products Quality Supervision and Inspection Center (Jinan) collaborated with Shandong University to observe the migration of nanosilver from commercially available food fresh container (Huang and others 2011). They used the nanosilver LDPE bag from Sunriver Industrial Co., Ltd. which is available in the Chinese market. First, the total amount of silver in the sample was quantified by microwave digestion. The samples were submerged in a mixed solution of 5 mL nitric acid and 2 mL of hydrogen peroxide and then put in a microwave digestion oven. Under optimized conditions, the result showed that the fresh plastic bag contained 100 µg of silver in 1 g of LDPE. For the migration simulation, according to the Chinese standard GB/T 5009.60-2003, samples were tested using simulating solutions; ultrapure water, 4% acetic acid, 95% ethanol, and hexane. Samples were kept for 15 d at room temperature and in an oven at 40 and 50 °C, and were collected at intervals of 3, 6, 9, 12, and 15 d for analysis. As a result of Atomic Absorption Spectroscopy (ASS) analysis, it was found that the amount of silver migration was significantly increased by time and temperature in all food simulating solutions. They suggested the possible mechanism for this migration phenomenon in two steps. The initial release must be from the encapsulated nanosilver particles which are on the specimen surface layers. Then, the subsequent release of nanosilver took place by dual-sorption process, diffusion and embedding. The water and organic molecule is firstly embedded in the interlamellar regions and ultimately plasticize and widen the interspace between polymer chains. This can facilitate the following diffusion of simulants and change the overall crystalline state with simultaneous oxidation of nanosilver. The sorption equilibrium induces the mobility of the macromolecular chains, particularly in the amorphous region. Finally, the oxidized nanosilver can cross the diffusion barrier and migrate through the equilibrated specimen (Huang and others 2011).


**Table 1—Examples of currently available nano-food packagings and containers in the market.**

Nanomaterial type	Polymer type	Trademark or commercial product name	Improved functionality from product claim	Application or product image
Nanoclay	Nylon 6	<ul style="list-style-type: none"> <li>- Aegis® OXCE Barrier Nylon Resin</li> <li>- Product from USA</li> <li>- Honeywell International Inc.</li> </ul>	<ul style="list-style-type: none"> <li>- Aegis® OXCE barrier nylon resin provides an excellent barrier which is comparable to the glass bottles performance.</li> <li>- Aegis® OXCE barrier nylon resin is well suited to the co-injection process because its recommended processing temperature is similar to that of PET.</li> </ul>	<p>-1.6 L Hite Pitcher beer bottles from Hite Brewery Co. (South Korea)</p> 
Nanoclay	Nylon 6	<ul style="list-style-type: none"> <li>(1) Imperm® Nylon nanocomposite</li> <li>(2) Product from USA</li> <li>(3) Mitsubishi Gas Chemical Company, Inc.</li> </ul>	<ul style="list-style-type: none"> <li>- Imperm® can replace the EVOH with a more cost effective material that allows for easier processing and maintaining barrier properties.</li> <li>- Imperm® eliminated the need for tie-layers.</li> </ul>	<p>-500 mL beer bottles from Miller Brewing (U.S.A.)</p> 
Nanoclay	Starch	<ul style="list-style-type: none"> <li>(1) Plantic® Plastic Tray</li> <li>(2) Product from Australia</li> <li>(3) Plantic Technologies Limited</li> </ul>	<ul style="list-style-type: none"> <li>- Plantic® Plastic Tray is made from renewable and sustainable resources that are non-toxic to the environment and biodegradable after use.</li> <li>- The nanocomposite material has improved mechanical and rheological properties and reduced sensitivity to moisture in that the rates of moisture uptake and/or loss are reduced.</li> </ul>	<p>-Thermoformed Plantic® trays for: Cadbury® Dairy Milk™ and Mark&amp;Spencer Swiss Chocolate</p> 
Nanosilver (particles size 25 nm)	PP	<ul style="list-style-type: none"> <li>(1) FresherLonger™ Plastic Storage BagsFresherLonger™ Miracle Food Storage</li> <li>(2) Product from USA</li> <li>(3) Sharper Image® Company</li> </ul>	<ul style="list-style-type: none"> <li>- Keep foods fresher 3 or even 4 times longer for fruits, vegetables, herbs, breads, cheeses, soups, sauces, and meats.</li> <li>- In tests comparing FresherLonger™ to conventional containers, the 24 h growth of bacteria inside FresherLonger™ containers was reduced by over 98%.</li> </ul>	
Nanosilver	PP, silicon	<ul style="list-style-type: none"> <li>(1) Sina Antibacterial Food Storages</li> <li>(2) Product from Vietnam</li> <li>(3) Dai Dong Tien Corporation</li> </ul>	<ul style="list-style-type: none"> <li>- Prevent from dirt and fungus.</li> <li>- Removing bad smell and prevent germs growth.</li> <li>- Keep foods fresher and longer.</li> </ul>	
Nanosilver	PP, Copolyester (Tritan™)	<ul style="list-style-type: none"> <li>(1) e.Window® Nano Silver Airtight Container</li> <li>(2) Product from South Korea</li> </ul>	<ul style="list-style-type: none"> <li>- Against odor.</li> <li>- Nanosilver additives help to sterilize food containers and reduce bad smells as the result.</li> <li>- Approved by USFDA.</li> </ul>	
Nanosilver	N/A	<ul style="list-style-type: none"> <li>(1) Everin Food Containers Nano Silver Airtight</li> <li>(2) Product from South Korea</li> <li>(3) NewLife Co., Ltd.</li> </ul>	<ul style="list-style-type: none"> <li>-The silicone seal contains antibacterial nanosilver particles that kill harmful bacteria, keeping food fresher for longer.</li> </ul>	

(Continued)





**Table 1–Continued.**

Nanomaterial type	Polymer type	Trademark or commercial product name	Improved functionality from product claim	Application or product image
Nanosilver	Copolyester (Tritan™)	<ol style="list-style-type: none"> <li>(1) Incense Nano Silver Food Container</li> <li>(2) Product from South Korea</li> <li>(3) Dong Yang Chemical Co., Ltd.</li> </ol>	<ul style="list-style-type: none"> <li>- Silver was scientifically proven anti-bacterial material. So, it naturally inhibits the growth of bacteria, viruses or fungi on the surface of container.</li> <li>- The effectiveness of silver was shown through independent laboratory tests which 24 h growth of bacteria in nanosilver containers was reduced the bacteria 99.9%.</li> <li>- Antifungal capacity 99.9% (developed by Pohang University of Science and Technology).</li> </ul>	
Nanosilver (particles size 20 to 70 nm)	PE	<ol style="list-style-type: none"> <li>(1) Fresh Box Nano Silver Food Container</li> <li>(2) Product from South Korea</li> <li>(3) FinePolymer, Inc.</li> </ol>	<ul style="list-style-type: none"> <li>- FreshBox is a newly developed nanosilver antimicrobial food container which made by unique nanotechnology.</li> <li>- FreshBox shows excellent antimicrobial properties against various bacteria and fungus due to the effect of finely dispersed nanosilver particles and hence it makes a food fresh longer compared with conventional food containers.</li> </ul>	
Nanosilver	PES, PP	<ol style="list-style-type: none"> <li>(1) BabyDream Silver-nano Noble product lines: nursing bottle, safe pacifier for newborn and one-touch mug cup</li> <li>(2) Product from South Korea</li> <li>(3) Babydream Co., Ltd.</li> </ol>	<ul style="list-style-type: none"> <li>- Feeding bottles and mug cups developed with this technology help protect babies with weak immunity from germs, the source of all diseases.</li> <li>- This perfectly prevents Secondary Virus Inflammation by controlling germs, and acting as an anti-bacterial deodorant, and maintaining freshness up to 99.9% without additional disinfecting by boiling and sterilization.</li> </ul>	
A silver-base zeolite antimicrobial agent	PP, PS, ABS	<ol style="list-style-type: none"> <li>(1) Zeomic</li> <li>(2) Product from Japan</li> <li>(3) Sinanen Zeomic Co., Ltd</li> </ol>	<ul style="list-style-type: none"> <li>- Antimicrobial (bacteria, enzyme, and molds).</li> <li>- To kill pathogenic organisms, reducing their number to an extent that is not harmful, and making them harmless by removing their infectability.</li> </ul>	-Plastic films for food packaging
Nanosilver	PP, PE	<ol style="list-style-type: none"> <li>(1) Anson Nano Freshness-Keeping Film</li> <li>(2) Anson Nano Freshness-Keeping Storage Bag</li> <li>(3) Anson Nano Silver Fresh Containers</li> <li>(4) Product from China</li> <li>(5) Anson Nano-Biotechnology (zhuhai) Co., Ltd.</li> </ol>	<ul style="list-style-type: none"> <li>- Keeps foods fresh longer.</li> <li>- Combining nanosilver with food grade, it is safe for storage of foods and vegetables.</li> <li>- American FDA standard.</li> </ul>	

(Continued)

Table 1–Continued.

Nanomaterial type	Polymer type	Trademark or commercial product name	Improved functionality from product claim	Application or product image
Nanosilver	PP, silicon	(1) Nano Silver Food Container (2) Product from China (3) Cixi Mingxin Plastic & Rubber Factory	<ul style="list-style-type: none"> <li>- Nanosilver made using nanotechnology to bond materials at a molecular level can help keeping your costly foods fresher longer.</li> <li>- Nanosilver food containers have long been considered a powerful and natural antibiotic and antibacterial.</li> <li>- Silver works differently than most other substances as it interferes with enzyme from single celled bacteria.</li> <li>- The organisms do not develop a resistance to silver like they do to other agents.</li> </ul>	
Nanosilver	PP, silicon	(1) Double handle nanosilver baby bottle (2) Product from China (3) Shenzhen Ibecare Commodity Limited Company.	-Food grade PP material and nanometer silver antibacterial agent, BPA free.	

Echegoyen and Nerin (2013) also investigated the migration of nanosilver from commercially existing food containers which are claimed to be microwavable. Three brands of products from the US market were collected for this test: Kinetic Go Green Basic Nanosilver Food Storage containers, Oso Fresh Food Storage containers, and FresherLonger™ Plastic Storage bags. The test was carried out according to EU Regulation - No.10/2011: on plastic materials and articles intended to come into contact with food, and the released nanomaterials from packaging were measured by ICP-MS. The containers were filled with 50% (v/v) ethanol and 3% (v/v) acetic acid as a food simulant followed by testing under 2 different experimental conditions: microwave oven at 700 W for 2 min and conventional oven at 40 °C for 10 d. Among the three samples, Kinetic Go Green showed the highest migration value in both conditions and a greater number of released particles were obtained in the microwave oven. Based on their study, the amount of nanosilver migration in all cases was under the maximum limitation according to the European Union (EU) legislation. However, there is no particular legislation for metal nanomaterials which is of concern because of the difference in toxicity with respect to the bulk material.

Not only the migration of inorganic metal such as silver has been investigated, but also the migration of natural base nanomaterials such as microcrystalline cellulose or nanoclay has been observed. Fortunati and others (2012) have studied the migration properties of modified cellulose nanocrystal in polylactic acid (PLA). They found that the migration level of cellulose nanocrystal in isooctane was higher than in 10% (v/v) ethanol, although this was lower than the limitation of the EU legislation. In addition, Farhoodi and others (2014) studied the migration of nanoclay from PET stretch blow-molded bottle. Their results showed a relationship between aluminum and silicon concentration in the acetic acid solution and

time–temperature. The migration amount was higher when time and temperature was increased. Schmidt and others (2011) have performed migration study of nanosized layered double hydroxide (LDH) platelets from melt-extruded PLA nanocomposite films prepared with laurate-modified magnesium (Mg) – aluminum (Al) layered double hydroxide (LDH-C<sub>12</sub>). According to a European standard method for food contact materials, the composite films were tested for total migration and specific migration of LDH, laurate, and PLA oligomers using fatty food simulant, 95% ethanol and 5% water, at 40 °C for 10 d. As a result, migration of nanosized LDH was observed with significant reduction of PLA molecular weight in all composite films. However, migration quantity was lower than the total migration limits as set down by the EU legislation. They also found migration of tin and laurate organomodifier that used in PLA masterbatch, indicating that it is quite critical to address the simultaneous migration of other chemical additive such as stabilizer and nucleating agent. Di Maio and others (2013) found that the dispersal of clay platelets induces the discrete zone in homogeneous PLA which facilitates the simulants easily penetrate and diffuse into polymer matrix. This relaxation and opened structure influence the decrease of the mass transfer resistance of potential migrants. Besides, Simon and others (2008) presented a modeling approach to estimate the migration behavior of nanoparticles and predicted the migration of nanoclay from PET – beer bottle as no detectable migration of clay from PET matrix will be found. According to their model, migration will only be occurred under the specific case; a very small particle with order of 1 nm radius combined with a relatively low dynamic viscosity polymer.

Lin and others (2014) studied the effect of particle size on the migration behavior of TiO<sub>2</sub> in LDPE food packaging films. They tested 2 different sizes of TiO<sub>2</sub>, 30 and 100 nm in diameter, with food simulants. As a result, 100 nm TiO<sub>2</sub>-LDPE showed

slightly larger amount of migration as the migration behavior is highly dependent on the compatibility of the nanoparticles with the solid (film) and liquid (food simulant) phase. The compatibility of nanoparticles in polymer matrix tends to decrease with increase of their size and thus, 100 nm TiO<sub>2</sub> migrated more into food simulant in this study.

Among many migration studies, a study by Bott and others (2012a) provided a view contrary to this idea of nanoparticle migration. This research was conducted under the Bavarian Authority for Public Health and Food Safety project on nanotechnology related food safety. It was brought to the public by Roland Franz, who is head of the department of product safety and chemical analysis at the Fraunhofer IVV institute based in Germany, in European Food Safety Authority (EFSA) scientific opinion forum in Parma, 2012 and in a presentation of Parliament in Brussels, March 2013 (EFSA 2012; Bott and others 2012a; Bott and others 2012b). In the first experimental model, TiN was selected because it is widely used in PET bottle production. LDPE was used as a polymer matrix because it allows for the highest mobility of migrants and hence it can be considered to be the worst case matrix. Film samples were prepared by blending LDPE with spherical shape nano-TiN masterbatch in different concentrations: 0, 100, 500, and 1000 ppm. Then, all samples including the control (blank) were soaked in food simulants at 60 °C. Food simulants used in this study were 3% acetic acid, 95% ethanol and iso-octane. After 10 d of aging, they found that the migration amounts were not significant between controls and specimens. From ICP-MS, the Ti migration from the 1000 ppm sample was detected in the highest range, 0.025 to 0.027  $\mu\text{g}/\text{dm}^2$ , whereas the 100 and 500 ppm sample showed migration amounts between 0.022 and 0.024  $\mu\text{g}/\text{dm}^2$ . Moreover, there was no migration found in ethanol and iso-octane in all samples. In addition, Bott and team conducted another experimental model by incorporating nanosilver with LDPE film in three concentration levels: 50, 185, and 250 ppm. This research concluded that there was no evidence of migration of nanopolymer from LDPE polymer matrix into food simulants, even though the experiments were conducted under very severe test conditions. From these exhaustive experiments, EFSA and PlasticsEurope, the association of plastics manufacturers in Brussels, consequently concluded that the risk of nanomaterial migration in food contact containers and plastics packaging is negligible (EFSA 2012; Bott and others 2012a; Bott and others 2012b; Banks 2013).

In addition to migration investigations, the detection or identification method of nanoparticles poses challenges. In 2011, Lin and others examined nanosilver in food packaging by microwave digestion coupled with inductively coupled plasma atomic emission spectroscopy (ICP-AES) and ICP-MS. They found the most critical step is the sample digestion. Moreover, from their results, they suggested the use of ICP-MS to detect the migration of nanosilver from food packaging because it provides more accuracy when compared with ICP-AES. In 2012, Liu and others published an article on methods for separation, identification, characterization, and quantification of silver nanoparticles. They argued that both ICP-AES and ICP-MS are efficient and quick methods to determine nanosilver quantities. However, these methods have a drawback in that sample tips can be blocked or clogged with the presence of particles in the spray chamber. In addition, atomization can be hindered by other organic substances. Therefore, the pre-separation step is required before digestion; otherwise, silver ion cannot be distinguished. As a result, they concluded that the current methods to detect nanosilver in the environment have

poor sensitivity. It is important to develop an effective method since the concentration of migrated nanoparticles is very low. Therefore, separation, characterization, and quantification need to be improved. Cushen and others (2013) cited the report by Liu and others (2012) and EFSA (2012) endorsing that there are complexities and variations in the detection, characterization, and quantification of migrated nanomaterial in real foodstuff. Sample digestion is still required as the disturbed organic substance must be removed. Nevertheless, there is a possibility that some ions remain and are present in pre-digestion. As a result, the device will measure these ions and migrated particles without distinction, and subsequently, the analysis results will have low accuracy.

### Food Packaging/Containers with Nanomaterials and Public and Media Perceptions

According to recent studies, nanoparticles can migrate from packaging into foodstuff. Although the observed amount of nanomaterial migration is lower than the migration limit in legislation, the regulation was written only for general substances, and the table does not cover all the types of nanomaterials which exist in the market (European Commission 2011). Until their safety has been fully established, the public may still have questions as to their possible health impact. Several media outlets and non-governmental organizations (NGOs) have brought up this issue via their communication channels.

In February 2013, The New York Times published a report from a nonprofit group, As You Sow, detailing which nanomaterials are being used in food products and packaging from well-known producers, even though only a few companies have publically acknowledged their use. Out of 2500 surveyed companies, only 26 companies, including PepsiCo and the corporate owners of Pizza Hut and Taco Bell, responded to the survey. Only 2 companies demonstrated that they have policies in place with regard to the use of nanomaterials, whereas 14 companies insisted that they do not use nanomaterials. In their report, As You Sow stated that although they were not against the use of nanotechnology, safety assessments, and proof of safety are needed prior to further use with food and food packaging because the USFDA cannot yet prove whether or not this technology is risk-free, and they put the burden of proof back on industry to make this determination (Stephanie 2013). Prior to the New York Times report, in December 2011, FoodProductionDaily.com stated that the USFDA had yet not established any solid regulation to confront nanomaterial risk in the food sector (Astley 2011).

In April 2013, FoodProductionDaily.com revealed a study by Cushen and others (2013) about the migration of nanosilver from PVC to chicken meat. The results showed that the migration level was below the regulatory limit; however, the effects of these migrated nanomaterials remain unclear. Risk assessments on nanosilver are in progress since sufficient toxicological data are not yet available in the EU (Whitworth 2013).

Wagner (2013) presented an article on nanomaterials on the Foodpackagingforum.org website addressing the current status of regulation in the U.S.A. and the EU as of 2013. In the U.S.A., the USFDA is the main organization responsible for this regulation. Some nanomaterials are listed as Generally Recognized As Safe (GRAS) for food containers, such as carbon black, aluminum, nanoclay, and zinc oxide, and thus, do not require pre-market authorization. Generally, the USFDA has taken the view that nano-additives may be used without further notice if the quantities do not exceed the specified limitations. However, this announcement

is ambiguous about the types of nanomaterials which are currently used in the supply chain for food contact materials. On the other hand, with regard to EU regulation, only three nanomaterials have been authorized for use in plastic food packaging, including carbon black, TiN, and silicon dioxide. Nanoclay, silver, aluminum, and zinc oxide have not been authorized in the EU. In 2011, EFSA published a guidance document “Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain” (EFSA 2011), which indicated what physicochemical information is required from manufacturers. It requests *in vitro* genotoxicity, absorption, distribution, metabolism, and excretion (ADME) tests and a repeated-dose 90-d oral toxicity study (Wagner 2013).

However, the Plastics Europe organization and the Parliament Magazine published a different view in a parliament debate in March 2013. They commissioned experiments and investigations on the migration of nanomaterials from plastic packaging to food for the EU parliament. Their testing revealed that the use of nanomaterials in food packaging is safe and convenient because of extremely low migration. This experimental work and proposal was supported by Vittorio Prodi, an Italian deputy (Banks 2013).

### Current Status of National Regulations and Legislation for Nano-food Packaging

In 2009, The Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) held a conference titled “Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications” (FAO/WHO 2010; Takeuchi and others 2014). Experts from 13 countries around the world, including Australia/New Zealand, Brazil, Canada, China, the European Union, Indonesia, Japan, Malaysia, Mexico, the Republic of Korea, South Africa, Switzerland, and the United States attended this meeting. They all shared the same concerns about the lack of knowledge of the human health effects of nanomaterial applications, and called for the early consideration of its safety. The meeting provided information on existing and emerging applications of nanotechnologies, including what is known about the food safety implications as well as any potential risks and the current capacity to assess such risk. It was expected that a medium-term plan for further work would be formulated to accurately assess and foresee risks. “Nano-enabled food contact materials (FCMs) and packaging” was included as a topic at the meeting. The FAO and the WHO declared their intent to provide guidance and advice to national governments on specific issues related to food safety. Following the meeting, the participants agreed that nanotechnology provides considerable benefits and opportunities for innovative product development, for water treatment, agriculture, food processing, packaging, and preservation. However, the definition of terms in the area of food must be clear in this international discussion, and this gap could be addressed by the Codex Alimentarius Commission (FAO/WHO 2013).

In 2012, the FAO and the WHO released a draft paper titled “State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors” for comments (FAO/WHO 2012). The aim of this paper was to follow up with each country on the recommendation of the previous expert meeting in 2009 regarding their regulation of food safety. This report summarized the recent activities in risk assessment and management of nanomaterials in the food and agriculture sectors at the national and international level. It also included the current status of nanomaterial

applications in food packaging as a new technology solution to reduce food loss or to facilitate traceability. In addition, the progress and current situation of nano-safety management in the participating countries was described. Table 2 summarizes relevant activities at the national level and further details are described at the following section.

### North America

In 2009, the United States Environmental Protection Agency (EPA) developed a nanomaterial research strategy, as the use of nanomaterials is rapidly expanding. The EPA identified types of nanomaterials which are typically used in products and selected six nanomaterials to be tested. The Organization for Economic Cooperation and Development (OECD) performed the analysis and determined the possible effects on human health and the ecosystem. Nanosilver and nanotitania were included in this research as representatives of food packaging applications (USEPA 2013; FAO/WHO 2013). In June 2011, the USFDA released a draft guidance report for the public with regard to FDA-regulated products containing nanomaterials or otherwise involving the use of nanotechnology (USFDA 2011; Adams 2012). This document does not establish any regulatory definitions, but is intended to help manufacturers and their stakeholders understand that they should consider the potential implications, safety concerns, and public health impacts which may result from the use of nanomaterials in their FDA-regulated products.

Then, in October 2011, the National Nanotechnology Initiative (NNI) issued a national strategy for ensuring the responsible development of nanotechnology and to support regulatory decision-making, replacing the 2008 national strategy (FAO/WHO 2013). The report focused on environmental, health, and safety concerns. However, this report argues that more research is required to determine the physicochemical properties of nanomaterials, as well as measurement and monitoring methods for nanomaterials in realistic exposure media. In June 2014, the USFDA launched “Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives” (USFDA 2014b). This document provides guidance to manufacturers of food ingredients and food contact substances (FCSs), and end users of food ingredients and FCSs, including food ingredients that are color additives. In such circumstances, the USFDA generally recommends that manufacturers should study and prepare a comprehensive toxicology profile. This document referred to the Code of Federal Regulations, Title 21 (21CFR 170.39). A substance used in a food-contact article such as food packaging or food-processing equipment that migrates, or that may be expected to migrate into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if the substance satisfies certain criteria relating to (USFDA 2014a):

- its potential carcinogenicity;
- the estimated dietary exposure to the substance;
- its lack of technical effect in or on the food to which it migrates; and
- its lack of significant adverse impact on the environment

In March 2014, EPA took action to prohibit sale of plastic food containers containing nanosilver produced by Pathway Investment Corp. since their products have never been tested or



**Table 2—Summary of current status of regulations and legislation on nanomaterials in food packaging by country.**

Continent	Country	Current status	Next action plan
North America	USA	<ul style="list-style-type: none"> <li>- In 2009, the EPA identified 5 nanomaterial types for investigation that are widely used in products or have been recognized for their potential uses. Nanosilver was observed in terms of food packaging material (USEPA 2013).</li> <li>- In 2012, the USFDA published “Regulatory Approach to Nanotechnology In Food Contact Substances,” focusing on food packaging (Adams 2012).</li> <li>- In June 2014, the USFDA issued a “Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives” (USFDA 2014b).</li> </ul>	<ul style="list-style-type: none"> <li>- This “Regulatory Approach to Nanotechnology In Food Contact Substances” guidance is currently being prepared (Adams 2012).</li> <li>- The EPA identified types of nanomaterials which are typically used in products and the material being studied include TiO<sub>2</sub>, AgNPs, CTNs, cerium oxide, and fullerenes (Takeuchi and others 2014).</li> </ul>
North America	Canada	<ul style="list-style-type: none"> <li>- Regulations in Canada make no explicit reference to nanomaterials at this time. Health Canada helps protect and promote health by using existing legislative and regulatory frameworks to mitigate the potential health risks of nanomaterials and to help realize their health benefits (FAO/WHO 2013).</li> </ul>	N/A
North America	Mexico	<ul style="list-style-type: none"> <li>- No safety assessments or regulations specific to nanomaterials in food, food-related or agriculture sectors were found on government web sites relating to food and agriculture (FAO/WHO 2013).</li> <li>- In 2012, the Mexican Secretary of Economy released a set of guidelines for the regulation of nanotechnology and nanomaterials which was duplicated and aligned from guidelines provided by U.S. authorities. The main intent of this guideline is on facilitating trade (Foladori and Lau 2014).</li> </ul>	N/A
South America	Brazil	<ul style="list-style-type: none"> <li>- In 2011, experts from the Brazilian Competitiveness Forum on Nanotechnology met in São Paulo to address the issue of regulating nanotechnology for the industrial sector (NIA 2011). The meeting was attended by representatives of the working groups of the forum, who discussed a study funded by the Brazilian Agency for Industrial Development on the development of possible standards, laws, and guidelines for nanotechnology regulation in Brazil (FAO/WHO 2013; Takeuchi and others 2014).</li> <li>- In 2013, the 1<sup>st</sup> bill for labeling of food and drugs containing nanostructures was rejected by the Brazilian Congress (Almeida 2013).</li> </ul>	<ul style="list-style-type: none"> <li>- As the first bill was rejected in 2013, experts in Brazil are developing a new proposal for nanomaterial-labeled products which will be submitted to Congress soon (Almeida 2013).</li> </ul>
Africa	South Africa	<ul style="list-style-type: none"> <li>- No safety assessments or regulations specific to nanomaterials in the food and agriculture sectors were found on the Government of the Republic of South Africa’s website (FAO/WHO 2013).</li> </ul>	<ul style="list-style-type: none"> <li>- South Africa’s National Nanotechnology strategy and Nanotechnology Innovation Centers were established for supporting the long-term nanoscience research (FAO/WHO 2013; Department of Science and Technology of the Republic of South Africa 2014).</li> </ul>
Europe	Switzerland	<ul style="list-style-type: none"> <li>- There is no Swiss legislation that incorporates specific safety provisions for nanomaterials (FAO/WHO 2013). However, the Federal Office of Public Health and the Federal Office for the Environment in Switzerland published a precautionary matrix to assist authorities, industry, trade, and commerce and research laboratories in the preliminary clarification of any need for action (FAO/WHO 2013; Takeuchi and others 2014).</li> </ul>	N/A

(Continued)

Table 2–Continued.

Continent	Country	Current status	Next action plan
Europe	EU	<p>In 2011, the EFSA published a scientific opinion entitled “Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain” (FAO/WHO 2013). Four nanomaterials have been studied:</p> <ol style="list-style-type: none"> <li>(1) silicon dioxide (Food Packaging Related)</li> <li>(2) titanium nitride (Food Packaging Related)</li> <li>(3) silver hydrosol</li> <li>(4) calcium carbonate</li> </ol> <p>There is no particular legislation in the EU concerning nanomaterials for food contact or food packaging. However, there is related existing legislation. Therefore, producers or manufacturers must comply with these existing regulations or legislation:</p> <ul style="list-style-type: none"> <li>- Commission Regulation (EU) No 202/2014: On materials and articles intended to come into contact with food and repealing (European Commission 2014).</li> <li>- Commission Regulation (EU) No 1282/2011: On plastic materials and articles intended to come into contact with food (European Commission 2011).</li> <li>- Commission Regulation (EC) No 975/2009: relating to plastic materials and articles intended to come into contact with foodstuffs (European Commission 2009b).</li> <li>- Commission Regulation (EC) No 450/2009: On active and intelligent materials and articles intended to come into contact with food (European Commission 2009a).</li> </ul>	N/A
Asia	Russian Federation	All industries who use nanomaterials must follow with the Regulation of the Chief State Health Officer of the Russian Federation dated July 23, 2007 N 54 (FAO/WHO 2013).	Risk evaluations have been performed since 2012. Research is ongoing. The results will be used for new regulations (FAO/WHO 2013).
Asia	China	<ul style="list-style-type: none"> <li>- No specific regulation about nanomaterials for food packaging ([FAO/WHO] Food and Agriculture Organization of the United Nations / World Health Organization 2013).</li> <li>- Until now (2014), applications for using nano-minerals or food ingredients have been rejected by regulatory authorities, but the safety evaluation of nanotechnology in foods continues to be discussed (FAO/WHO 2013; Takeuchi and others 2014).</li> </ul>	N/A
Asia	Japan	<ul style="list-style-type: none"> <li>- Nanotechnology was specified as one of the priority research targets in the third Science and Technology Basic Plan for 2006–2010 by the Japanese government (FAO/WHO 2013; Takeuchi and others 2014).</li> <li>- The Japanese Ministry of Health, Labor, and Welfare launched a 6-y program (2009 to 2014) called the “Research project on the potential hazards, etc. of nanomaterials” (FAO/WHO 2013).</li> </ul>	N/A
Asia	Korea	<ul style="list-style-type: none"> <li>- The Republic of Korea government released guidance on safety management of nano-based products in 2011. A new research plan for nanomaterial safety based on ‘The First Master Plan on Management of Nanomaterials Safety’ is effective for 2012 (Hwang and others 2012a; Hwang and others 2012b).</li> </ul>	<ul style="list-style-type: none"> <li>- The MFDS undertakes a variety of research related to nano-safety in food as well as food packaging and they are planning to propose new guidelines and safety regulations regarding to nano-food packaging within a few years (Hwang and others 2012a; Hwang and others 2012b).</li> </ul>

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Table 2—Continued.

Continent	Country	Current status	Next action plan
Asia	Malaysia	- No safety assessments or regulations specific to nanomaterials in the food and agriculture sectors were found on Malaysian government web sites (FAO/WHO 2013; Takeuchi and others 2014).	N/A
Asia	Indonesia	- No safety assessments or regulations specific to nanomaterials in the food and agriculture sectors were found on Indonesian government web sites (FAO/WHO 2013).	N/A
Oceania	Australia/New Zealand	<ul style="list-style-type: none"> <li>- There is no regulation or organization in Australia focused on nanomaterial for food packaging (FAO/WHO 2013).</li> <li>- FSANZ recently published an article describing its regulatory approach to nanoscale materials in the International Food Risk Analysis Journal (FAO/WHO 2013; Fletcher and Bartholomaeus 2011).</li> <li>- The primary focus is not on the size of the material per se, but on materials likely to exhibit physicochemical and/or biological novelty (FAO/WHO 2013).</li> <li>- At present, the approval process for new substances applied for food packaging are generally unnecessary if there is approval in the EU or US (Tager 2014).</li> </ul>	- FSANZ will not have a recommendation on the inquiry and prescription about the migration of nanomaterial from food packaging until mid-2016. And for a regulation, it will not be gazetted until February 2017 (Tager 2014).

registered with the EPA. Kinetic Go Green Premium Food Storage Containers and Kinetic Smartwist Series Containers were stopped selling accordingly from market due to their unverified public health claims. EPA Regional Administrator stated that “Claims that mold, fungus or bacteria are controlled or destroyed by a particular product must be backed up with testing so that consumers know that the products do what the labels say” (Martin 2014).

According to the FAO and WHO 2013 report, Canada does not have any regulation on nanomaterials at this time. Health Canada uses existing legislative and regulatory frameworks to promote health and minimize the health risks from nanomaterials. Health Canada supports and requests that stakeholders communicate with the responsible regulatory authority in the early stages of the development process, particularly for products which comprise nanomaterials, to discuss their product’s safety assessment (FAO/WHO 2013; Takeuchi and others 2014).

### South America

Brazil has been recognized as a leader in nanotechnology research in South America (Foladori and Invernizzi 2013; Kay and Shapira 2009; Foladori and Lau 2014). In August 2011, experts from the Brazilian Competitiveness Forum on Nanotechnology gathered together in São Paulo to discuss effective regulation of nanotechnology for the industrial sector, and also to develop possible standards, laws and guidelines for nanotechnology regulation in Brazil (FAO/WHO 2013; NIA 2011). In September 2013, a proposal for introducing a new label for all food, drugs, and cosmetics containing nanostructured materials was rejected by the Brazilian Congress because it was argued that a new label would harm companies that have invested in nanotechnology and as a result, they might withdraw plans for the sector’s development in the country. However, some experts argued that the regulation would make nanotechnology and its industrial applications more transparent and would provide a good basis for advancing research

and public support. In this light, a new proposal was created. The new proposal involves labeling all products containing nanotechnology without requiring other laws to change. Although the experts were confident that the new bill proposal would soon be approved (Almeida 2013), to date, there is still no update or progress report posted.

### Europe

The European Union is the central organization for nanotechnology and nanomaterial in Europe. In 2010, The European Commission published a report via their online channel for public comments; “Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015”. The public consultation objective was to invite expert views on needs in nanotechnology over the next 5 y (European Commission 2010). In 2011, the EFSA released “Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain”. This document addressed the potential risk of nanomaterials in the supply chain and declared that the chemical composition, physicochemical properties, interactions with tissues, and potential exposure levels need to be determined for risk assessments. However, the EFSA stated that the lack of suitable and validated test methods contributes to inaccurate identification and characterization of nanomaterials. Therefore, the EFSA encourages stakeholders to perform additional research and assessment because of these uncertainties and limitations (FAO/WHO 2013).

Regarding existing guideline, EU legislation limits the quantities which is used in food containers or packaging, and requires that migration study results be provided (European Commission 2007). While EFSA requires an assessment of substance migrations from food contact materials into food, referring to Article 10 of the EU Regulation - No.1935/2004 (European Commission 2004). The assessment should contain a sequence of tests including migration and a determination of substance risk to human health.

The substance or material will be listed as an approved food contact material when it passes this safety assessment.

The EU action plan on nanotechnologies for the next few years is currently being prepared. In December 2014, EU released “European Food Information to Consumers – Regulation (EU) No 1169/2011 on the provision of pre-packed food information to consumers on general food labeling and nutrition labeling”. However, the scope covers food ingredients only (FSA 2014). This new legislation combines 2 directives, 2000/13/EC and 90/496/EEC, into one legislation (European Commission 2013). Under this regulation, all food ingredients with a form of engineered nanomaterials must be indicated in the list of ingredients. The names of such ingredients must be followed by the word “nano” in brackets (FAO/WHO 2013). Since the new regulation does not cover nanomaterials in packaging or containers, the existing legislations and regulations (that is, Commission Regulation (EU) No 202/2014 and 1282/2011, Commission Regulation (EC) No 975/2009 and 450/2009) have only been a guideline and reference for producers or manufacturers.

## Africa

Regarding nanomaterials and the use of nanomaterials in food-related applications including food packaging, there is no safety assessment or specific regulation found on the government website of any country in Africa (FAO/WHO 2013; Takeuchi and others 2014). However, South Africa had established a National Nanotechnology Strategy and Nanotechnology Innovation Centers for the purpose of long term nanoscience research. This program was an important first step for South Africa to focus on expanding the nanoscience and nanotechnology research (Dept. of Science and Technology of the Republic of South Africa 2014).

## Oceania

Food Standards Australia New Zealand (FSANZ) addressed the safety of nanomaterials in an article titled “Regulatory Approach to Nanoscale Materials”, in the International Food Risk Analysis Journal, 2011 (FAO/WHO 2013; Fletcher and Bartholomaeus 2011). In November 2014, FSANZ decided to identify and manage any risk caused by chemical migration from nano-food packaging, based on the result of the industry packaging survey, which concluded that the current requirements for packaging in the legal code are inadequate (Tager 2014; FSANZ 2014).

## Asia

The Japanese government prioritized nanotechnology research in its Science and Technology Basic Plan for 2006–2010. In addition, the Ministry of Health, Labor, and Welfare released a 6-y plan (2009 to 2014) which focused on the carcinogenicity of nanomaterials, titled “Research Project on the Potential Hazards, etc. of Nanomaterials.” The Japanese organization released the survey results of risk assessment of the use of nanotechnology in the food sector in March 2010. It was concluded that specific safety regulations for nanomaterials are not required. Nevertheless, the report also concluded that if any health issues arise and need to be addressed, it will be necessary to first establish the methods and protocols for safety assessments (FAO/WHO 2013).

The government of the Republic of Korea released guidance on the safety management of nano-based products in 2011. The guidance was adapted to assure the benefit and safety for nanotechnology users and consumers of nanotechnology-based products, enhance social acceptance of nanotechnology-based products, and promote sustainable development of nanotechnology industries.

More recently, the Korean government promoted a new research plan for nanomaterials safety based on “The First Master Plan on Management of Nanomaterials Safety” effective between 2012 and 2016. The objectives of the new research are to establish a database for the assessment and analysis of nanomaterials, to establish a system for assessment of nanomaterial safety, to prepare a basis for systemization of nanomaterial safety management, and to cultivate professional manpower and form partnerships with stakeholders. The Korea Ministry of Food and Drug Safety (MFDS) is one of the ministries involved in this national project and is responsible for establishing data and a system for safety management and assessment of nanomaterials, especially those used in food, beverage, medicine, and their packaging. At present, the MFDS undertakes a variety of research related to nano-safety in food, as well as food packaging, and they are planning to propose new guidelines and safety regulations regarding nano-food packaging within a few years (Hwang and others 2012b; Hwang and others 2012a).

In Malaysia in 2011, the Nanotechnology Directorate called for strategic innovative and interdisciplinary research and a total of 20 projects related to nanotechnology in agriculture and food sector resulted from this meeting. The main point of each project was focused on health, safety, and environmental issues. To comply with any future global safety standards relevant to nanotechnology, Malaysia is codifying a clear national roadmap. However, there are currently no specific regulations applicable to the risk assessment of nanotechnology (Takeuchi and others 2014; FAO/WHO 2013).

In the Russian Federation, the Federal Service for Surveillance of Consumer Rights Protection and Human Well-Being has had control of the use of nanomaterials in industry areas since 2007, following the regulation of the Chief State Health Officer of the Russian Federation dated July 23, 2007: N 54 “On the supervision of produce, received with use of nanotechnologies and containing nanomaterials.” Under this federal program, a total of 50 standards and methods for safety assessment and risk evaluation were created and approved by the Chief State Health Officer of the Russian Federation. Methods for risk evaluation were developed by referring to the general recommendations and requirements of the OECD, EFSA, and the FAO/WHO since 2012. As result of the safety assessment, the on-hand data allows the identification of the possible toxic effects of titanium dioxides, silicon, aluminum and iron, nanostructured clays (nanoexfoliated clay), fullerene C60, and metal silver. The research results present a safety level for these nanomaterials when in contact with food or ingested by mouth (FAO/WHO 2013).

## Conclusions

Along with the increasing market trend of nanocomposited food packaging has come an increase in public concern over possible harm to human health. Many research studies have demonstrated the probable migration behavior of nanomaterials from the polymer matrix, but some experimental studies have demonstrated that the migrated quantity is quite low in relation to other migration rates. However, most of these studies were conducted with food simulants, and testing with real foodstuffs remains insufficient. With undefined toxicity level of nanoparticles, the lack of knowledge on human health effects and risk assessments may restrict the number of nanomaterial consumption in the food-related applications. Publishers and media outlets use their channels to communicate with consumers and provoke governmental agencies with regard to the national regulation of nanomaterials in food packaging. Although, the USA is a leading country in the development



of nanomaterial safety resources for food and food packaging, a definite regulatory approach to nanotechnology in FCSs by the USFDA is still in progress. Besides, the latest European Union legislation on nanomaterial safety published in 2014 does not yet cover nano-enabled food packaging. Each national government needs to address this issue, and more importantly, to take action for international cooperation in the pursuit of nano-safety alarming system since nanoparticles may well be difficult to detect in imported packaged goods that transfer from nation to nation. Legislation and guidelines should be developed and enacted to protect public health from the spread of nanomaterials in food-related applications and therefore, this issue should be addressed in the international planning policy framework.

## Acknowledgment

This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education (Grant No. 2013R1A1A2060023).

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