

food contact world

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food contact world is published 10 times a year. Each issue includes news and in-depth articles to keep food contact practitioners and experts updated on food contact issues around the world across all food contact packaging materials and applications.

Guarded view of BPA signals a regulatory shift

The Obama administration has drawn up an artful political compromise to deal with bisphenol A (BPA).

The US Food and Drug Administration (FDA) revealed the [new strategy](#) on the use of the substance in food contact applications during a much-anticipated briefing in mid-January.

The agency's position is highly nuanced with enough facets to mollify environmental activists, crusading reporters working for a small newspaper in the Midwest, and state legislators. All are campaigning hard for an outright ban on the chemical.

Reflecting an internal government disagreement over the danger of BPA, the FDA's policy decision was delayed for six weeks.

Appearing with a director at the National Institutes of Health (NIH) – the primary agency in the US for supporting medical research – FDA officials announced that they now shared 'some concern' about the potential effects of BPA on the brain, behaviour, and prostate gland in foetuses, infants, and young children.

The FDA's agreement with the NIH about the scientific literature on BPA is not much different than the opinion the agency has held all along (see *Food Contact World*, 16 September 2008).

The FDA 'is not recommending that families change the use of infant formula or foods, as the benefit of a stable source of good nutrition outweighs the potential risk of BPA exposure'.

On the scale of risks, 'some concern' is exactly half-way down the threat level. It means that the evidence is insufficient to draw a conclusion one way or the other and that additional research is needed.

The FDA and the NIH will partner on several studies designed to remove the doubts over the next two years.

'These uncertainties relate to issues such as the routes of exposure employed, the lack of consistency among some of the measured endpoints or results between studies, the relevance of some animal models to human health, differences in the metabolism (and detoxification) of and responses to BPA both at different ages and in different species, and limited or absent dose response information for some studies,' FDA explains.

Legal changes examined

The new position announced by the FDA does contain one pronounced

Joshua Sharfstein (pictured at a health summit in November 2009) says the FDA is interested in bringing BPA under the food contact notification process because it has more regulatory flexibility: 'We can require companies to submit additional safety and exposure data. We can require other types of studies, and if we are able to reach a conclusion [that] a revocation of one or more approved uses is justified, we can protect the public by revoking the use just through a notice published in the Federal Register.'



Source:
National Academy of Sciences

change. The agency has decided to shift to what it calls 'a more robust regulatory framework'. The agency wants the change to 'be able to move quickly if necessary, if new information becomes known'.

BPA is not regulated by

the FDA, but polycarbonate plastic and epoxy resins are, in 21 CFR 17.1580 and 21 CFR 175.300, respectively.

'If we wanted to change anything, like if we were to decide that it was necessary to revoke a major use of BPA, we would have to go through notice and comment rule-making,' says Josh Sharfstein, principal deputy commissioner of the FDA, commenting on the present legal situation governing the use of BPA.

So the FDA will encourage manufacturers to submit a food contact notification voluntarily for their currently marketed uses of BPA-containing materials (see the related article in this issue, on page 5).

The FDA says it will also explore additional options to regulate BPA under the more modern framework.

'We're looking at the question of whether we have the ability to force that switch under our current authority from the old way of doing it to the new way, and that may be quite difficult for the FDA,' Sharfstein says.

A final option is through legislation targeted at BPA. 'We have had a call with

congressional staff today, and you know it wouldn't surprise anyone to hear that that question came up. And I'm sure that will be a topic of discussion.'

Triclosan correction

As reported in the most recent issue of *Food Contact World*, the European Commission is beginning the paperwork to eliminate triclosan from the [provisional list](#) for use in food contact materials. But not for the reason stated.

The scientific panel on food contact materials, enzymes, flavourings and processing aids (CEF) at the European Food Safety Authority did not issue any new risk assessment for the antibacterial agent.

Triclosan is being scrubbed because no request is pending to use the substance in food contact materials.

In 2009 Ciba, which is now part of BASF, withdrew the chemical 2,4,4'-trichloro-2'-hydroxy-diphenyl ether for consideration in food contact materials.

It is true that the German Federal Institute for Risk Assessment (BfR) had previously [recommended](#) minimising exposure to triclosan. The Commission's decision, however, is, strictly speaking, an administrative one.

Small nation but big steps

Despite its size (population less than 900,000) and the absence of a food safety authority, Cyprus has laid strong foundations to comply with EU food contact material laws.

Special attention paid to ceramics since the island entered the EU in 2004 has resulted in zero violations in 2009.

Cypriot ceramics, especially the traditional brown variety, are important to the economy as well to consumer safety. In recent years, the local industries have received advice on proper furnace operation, the quality of raw materials, and the need to use only additives low in heavy metals and other materials.

Buoyed by the success of this initiative, the [State General Laboratory](#), a department of the Ministry of Health, is expanding its surveillance and critical control point strategy to imported multilayer plastic sheets, paper, and cellulose in large stores and markets.

The official national food laboratory has responsibilities beyond research and control. It performs risk assessments and advises government authorities. There are ambitions to evolve it into an institution with state-of-the-art approaches and regulatory transparency.

The recent record for other materials is mixed. In 2008, 40% (10 of 25 samples) of black nylon kitchen utensils failed migration tests for primary

aromatic amines, and 25% of plastic gaskets on lids from Egypt contained too much bis(2-ethyl hexyl phthalate (DEHP). Elleni Ioannou-Kakouri, senior chemist and quality manager at the lab, reports that 18% of cling films (3 of 16 samples) were not in compliance for di-(ethylhexyl)adipate (DEHA) in 2009.

Cyprus is almost entirely dependent on rainfall for its water, and there is not enough of it. In 2009, 62 samples of four brands and different lot numbers of imported bottled water for babies were sampled from high-density polyethylene (HDPE) and polyethylene terephthalate (PET) containers.

The highest concentration of DEHP was 187µg/L. A one-year-old (10kg) consuming two litres per day would exceed 10% of the tolerable dietary intake of DEHP set by the World Health Organisation and the European Food Safety Authority.

Ioannou-Kakouri says stricter controls will be used on the island to meet requirements related to traceability, declarations of compliance and good manufacturing practice.

DG Sanco audits compliance

From 2004 through to December 2009, 330 notifications through the rapid alert system for food and feed (Rassf) were made for non-compliant food contact materials that originated in

member nations of the EU.

During the same period, 689 notifications were made for food contact materials coming from developing nations. Most of the violations were by China, Hong Kong, Thailand, India, and Turkey.

The main hazards found are isopropylthioxanthone (ITX), benzophenone, primary aromatic amines (PAAs), formaldehyde, heavy metals, and phthalates, including phthalates from the lids of glass jars originating in developing nations.

Rafael Perez Berbejal, head of food hygiene and contaminants for the European Commission's Directorate-General for Health and Consumer protection (DG Sanco), recites the statistics to explain in part how the EU's Food and Veterinary Office (FVO) plans its inspection missions and in which countries.

The FVO is the department of DG Sanco, located in Grange, Ireland, which audits compliance with food safety legislation. Perez coordinates the inspection activities for food contact materials and additives.

The FVO was established in the wake of the bovine spongiform encephalopathy crisis in 1996. Its new series of missions started in 2007 and ends this year. In all, 20 member states will be inspected. FVO will eventually produce an

overview report.

In the context of food contact materials, FVO assesses the official control systems in place to prevent the migration of substances. The focus is on PAAs in plastics, lead and cadmium from ceramics, and formaldehyde from melamine kitchenware.

In Finland last year, for example, the mission team found that implementation of good manufacturing practices required under the EU directive [2023/2006](#) at two food contact material suppliers (plastics and ceramics) was low. A follow-up in September 2009 on a 2007 audit of food contact materials in China is yet to be published.

When the final version is

approved, all the audits are made available on the [Sanco website](#) alongside comments on the surveillance report from the competent authorities in the country and their response to the FVO's recommendations.

Several factors skew alert data by Rasff

In the first month of 2010, the EU rapid alert system for food and feed (Rasff) logged 15 food contact material violations.

Five happened to be notified by the UK for kitchen utensils (but one for phthalate in the lids of pickle jars) from India and China. Just about half (seven of 15) of the notifications

were for non-compliance by Chinese companies.

Just one of the January 2010 notices is not on the list of the usual suspects. Authorities in Finland warned consumers of white chocolates filled with truffle from France that are reddened by the colour on the outside wrapping.

Rasff notices are triggered by control procedures at border checkpoints or inspections on the EU market that determine prohibited or unauthorised substances, and migration exceeding legal limits. But Annette Schaefer, who has worked at the European Commission in the area of food contact materials since 2002, makes several points well worth considering when analysing Rasff data. She spoke at the latest annual conference held by Pira International on plastics and paper in contact with food.

Above all other factors clouding perceptions, the Rasff reports provide no clue as to the number of samples analysed and the percentage that are not in compliance. In addition, an alert by authorities in one country will cause others to step up their inspections of the same parameter. Conversely, member states often do not notify a non-compliance when it relates only to the local market.

Also influencing the Rasff results are missions undertaken to various countries by the auditing team from the Commission's Food and Veterinary Office (FVO). Schaefer

notes that the FVO auditing expeditions, as well as EU information policies on Rasff, can lead EU member nations to increase their notifications.

Chinese bioplastic destined for European tables

China Green Material Technologies, an equity security traded over the counter as CAGM, says it will enter the European market with corn-based biodegradable disposable tableware, including plates, bowls, and cups.

The company is headquartered in the city of Harbin and has fewer than 135 employees.

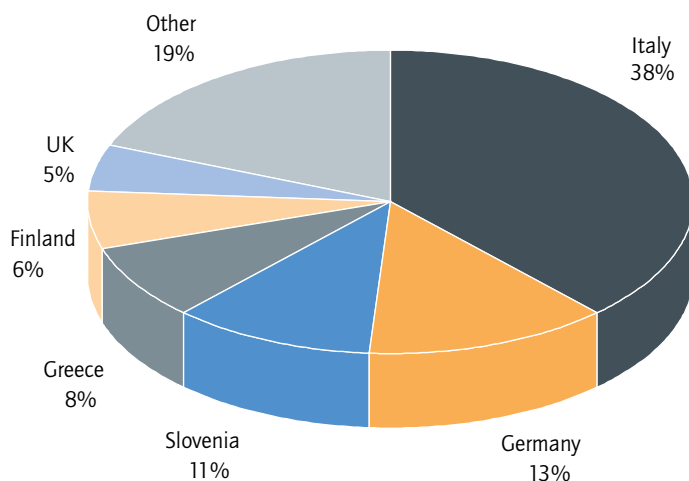
The firm closed a private placement in January 2010 with proceeds of \$4.5 million (€3.3 million).

The business is conducted through China Green Materials's 100%-owned equity ownership in ChangFangYuan Hi-Tech Environment-Friendly Industrial Company, incorporated in China.

The factory is certified to the international quality and environmental standards ISO 9001 and ISO 14001.

The CEO is Su Zhonghao who started the business in 2003. Before that he was associated with the Ocean Group, a venture capital outfit with roots in Ocean Airlines, a cargo operation based in Italy.

From 2004 to 2009, regulatory authorities in Italy have, on average, reported more non-compliances through the Rapid Alert System for Food and Feed than the inspection officials in any other member country



Source: DG Sanco

‘I have never seen anything like this before – Jerome Heckman’

Technology spotlight

Regulators are testing the weak link in the food supply chain

Political toxicology puts real pressure on industry

While government-funded scientists take a closer look at the safety of bisphenol-A (BPA) in fetuses and infants, the US Food and Drug Administration (FDA) wants to start moving to a ‘more robust’ regulatory framework for the chemical.

FDA’s intentions are clear

‘Basically, the message they are sending is to reformulate your products to get away from BPA,’ says Ralph Simmons, an attorney and litigator with 20 years’ experience representing companies on FDA matters. ‘They are using the power of the bully pulpit to get through to the customer base – to the food companies. FDA expects them to pass the message back [to their suppliers]. Either get out of BPA or submit a food contact notification and get FDA clearance.’

The shift is already taking shape, says Simmons based on what he sees happening in his own practice. His clients are working on alternatives.

Jerome Heckman, founder and senior partner of the law firm Keller and Heckman, is irate about the FDA’s decision. Heckman is credited

with helping establish the FDA’s food contact notification programme in 1997. Currently BPA in polycarbonate plastic and epoxy resins that come in contact with food has regulatory approval.

‘To put it mildly, I was and am shocked that FDA has put out a release suggesting that users of BPA file food contact notifications for their application. I am now a 60-year practitioner of food and drug law, and I have never seen anything like this before,’ he says.

‘It strikes me as particularly ill-advised when FDA is presently sponsoring and participating in a variety of studies to more accurately define what adverse effect, if any, BPA has had or will have. Moreover, every other country in the world that has considered the matter has decided that BPA presents no problem.’

‘It is clear to me that the only thing leading to FDA’s position is some rabble-rousing in the scientific community, led primarily by Dr vom Saal at the University of Missouri. All of the other countries, including Germany, France, and their neighbours have based concrete statements of no concern on the basis of studies done in Europe.’

Frederick vom Saal is a professor in the university’s Endocrine Disruptors Group. He has received more than \$1 million of the \$30 million that the government agencies have committed in the next two years to study health risks of BPA exposure (see the related story in this issue on page 2). Vom Saal says that the FDA’s new stance is a step forward but more of them are needed.

‘The FDA says it wants to respond more quickly. Now, we will see if they are really able to respond to the huge amount of new science showing dangers not recognised two years ago,’ vom Saal says in the belief that Congress will have to pass laws giving the FDA the authority it needs. ‘They should move quickly to restrict the use of BPA in products used by adults as well as infants.’

Heckman has coined a phrase for the lobbying effort. He calls it political toxicology. In a [treatise](#) on the subject, he says: ‘Unfortunately, the phenomenon of the raising of questions about materials, no matter how spurious, often, if not always, leads to the abandonment of a material by the food processor, and sometimes his retailer customers make this decision with little or no scientific basis so that there occurs a departure from use of the substance for reasons having no relationship to the science.’

BPA has proven to be exceptionally useful for linings of canned foods, like tomatoes, but Jerome Heckman maintains legislators in the US are leaping to introduce bills that ban using the ‘pseudo-scientific concept alluringly labelled the precautionary principle.’



Source: Pira International

Chemicals stain food pallets

Immediately after Democratic Party Congresswoman Chellie Pingree announced a [press conference](#) to introduce a [bill](#) in the US House of Representatives that would ban decabromodiphenyl ether, manufacturers inked an agreement with the US Environmental Protection Agency (EPA) to phase out the flame-retardant voluntarily by 2013.

The two US producers, Albemarle Corporation and Chemtura Corporation, and the largest importer, ICL Industrial Products, based in Israel, made the pledge.

Pingree wants to pursue the legislation anyway.

'We need to make sure that the industry doesn't start using another chemical that is just as dangerous as deca, so this bill has a provision to make sure that any alternative they come up with has to be safe,' she says.

Deca is used in plastic pallets to store and transport food. Intelligent Global Pooling Systems (IPGS), a rental service providing shippers and receivers with all-plastic pallets, has mounted a strenuous defence of its product against wooden alternatives.

The company has commissioned five separate sets of analyses of wood pallets with the same results across the country. Many are contaminated by

'The chemical industry hasn't always lived up to voluntary agreements. This bill will make sure they do,' Congresswoman Chellie Pingree says about her proposal to phase out deca-bde



Source: Congresswoman Chellie Pingree

bacteria and pathogens. Other independent tests have produced similar results (see *Food Contact World*, 12 January 2010).

The recent recall by Johnson & Johnson of tens of millions of bottles of over-the-counter medicines seemed to corroborate IPGS CEO Bob Moore's position.

A nausea-producing odour in the drugs is thought to originate with residues of 2,4,6-tribromanisole (TBA) from a preservative sometimes applied to wood pallets.

[Legislation](#) introduced in the state assembly of New York proposes to require all

pallets for food to be made of impermeable materials

'The evidence is irrefutable: wood pallets present dangerous risks to our foods and medicines,' says Moore.

The National Wooden Pallet and Container Association (NWPCA) charges that the plastic pallet industry is 'desperate to deflect customer attention – particularly that of food and drug producers – away from the very real hazards inherent in their product.'

NWPCA says the US wood industry and trading partners in Europe do not

use the TBA precursor 2,4,6-tribromophenol (TBP), but other countries do. Pharmaceutical companies are asking pallet suppliers for a certification that the wood and raw materials they use are free of TBP and not sourced from South America. Providing a chain-of-custody statement is a daunting proposition. NWPCA says it is talking with Johnson & Johnson about finding an acceptable and effective solution.

Ingredient improves recycled plastic

Ampacet has a new antioxidant masterbatch to protect reprocessed or recycled polyolefins from degradation during processing.

Blown and cast film can contain more recycle without detrimental effects on physical properties. The company says the masterbatch is particularly beneficial for clear packaging films.

The antioxidant masterbatch boosts thermo-oxidative stability. It protects recycled material against degradation, gel formation, and yellowing.

The masterbatch is also effective in repelletising operations, allowing recycled resin to perform more like virgin. It is approved for food contact applications.

Ampacet's development manager Shawn Lucas cites a case where adding 1% of the masterbatch allowed a cast film processor to increase repelletised material from less than 5% to more than 15%.

Ampacet is privately held and operates manufacturing sites in 11 countries.

Quick quiz on recycled papers

Sébastien Louvion, senior associate at Mayer Brown, offers this capsule explanation of EU law:

Q: Can I use recycled paper for food contact?

Yes, generally permitted.

Q: What are the main requirements?

Only general requirements: safety, good manufacturing practice.

Q: At the national level?

Generally must ensure same quality as virgin material. Some member states have more specific purity requirements or restrictions on types of recovered materials that can be used. Some member states have restrictions on the applications for which materials can be used. Use available resources (guidelines, trade associations) to generate suitable data.

Q: Are there any special labelling or declaration of compliance requirements?

No legally binding requirement to provide information on recycled content, although the Nordic countries are pushing for information to be included in a declaration of compliance.

Approval granted for microwaving packaged food

The US Food and Drug Administration (FDA) has approved the use of microwave energy for processing pre-packaged, low-acid foods.

Juming Tang, a professor in the Department of Biological Systems Engineering at Washington State University, led a team of researchers that produced the results. The team includes industry and military scientists.

The system designs were patented in October 2006.

Research administrators at Washington State University and food industry engineers think FDA approval could revolutionise processing. Juming Tang (left) discusses the microwave sterilisation technology on a short video



Source: Washington State Univ.

The group spent another three years developing a semi-continuous system, collecting engineering data, and microbiologically validating the process before receiving FDA acceptance.

Defence specialists believes the food processing technology will benefit soldiers in the field, not just ordinary consumers. The US Department of Defence combat feeding directorate at the Army Soldier Systems Centre in Massachusetts spearheaded the effort.

Tang says the outcome results in food with a longer shelf-life and better nutritional value compared with traditional food processing methods such as canning. The technology immerses the food in its package into pressurised hot water while simultaneously heating with a microwave at 915MHz. Food is penetrated more deeply than it is at the frequency used in home microwave ovens. The combination eliminates food pathogens and spoilage microorganisms in five to eight minutes.

The project has been funded from a variety of sources and a consortium of industry members: Kraft Foods, Hormel, Ocean Beauty Seafoods, Rexam Containers, Ferrite Components, and Graphic Packaging. The university team also worked with the Seafood Products Association in Seattle and Hormel to establish validation procedures and prepare filing documents.



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