

## Evolving regulatory affairs and sustainability – FPE in the vanguard



With the flexible packaging industry being subject to so many EU regulations there is constant and increasing need for dissemination of information and an understanding of how these regulations translate into business practices. Recognising this need Flexible Packaging Europe appointed John Dixon as its new Director Regulatory Affairs in May 2011.

This appointment increases the capacity to focus on, in particular, the ever changing and increasingly important food contact legislation. John has a distinguished career in the industry and is already a supporter of FPE in the FACET project and the newsletter FlexAffairs.

*More and more companies are now active in the FPE Technical Committee and John's new role will help to facilitate and co-ordinate work on regulatory issues across all areas of importance to FPE members.*

John replaces Gregor Spengler who was unable to increase his work capacity with FPE due to other commitments. FPE thanks Gregor for his great commitment and excellent work in the past.

Another appointment took place in March 2011 with Graham Holder taking up the role of Director Sustainability. Graham has over 20 years experience with a leading global brand owner and is applying his expertise to the vital area of sustainability issues and initiatives and the resulting ecological and economical benefits.

I am glad to announce the publication of the new FPE Thought Leadership Paper, "The Perfect Fit".

Flexible packaging offers the 'perfect fit' solution to sustainability challenges today. It provides a simple and adaptable answer to portioning, preservation and demands for convenience.

Simultaneously flexible packaging enables both the optimisation of packaging functionality and the best use of resources. This has the potential to provide considerable economic, environmental and social benefits. Effectiveness and efficiency are the fundamental factors that define the ultimate sustainability of a packaging solution.

*In the vanguard of the continually evolving 'sustainable packaging' agenda is flexible packaging solutions. It is often the closest to a 'perfect fit' in regards to the most sustainable solution available on the market.*

Visit [flexpack-europe.org](http://flexpack-europe.org) for the full report.

In summary, FPE has adapted its structure and developed a number of initiatives this year to meet the growing needs of its members. But without your involvement none of this would be possible. We count on your support and continue to look forward to hearing from you about what you expect from us and where our focus should be directed.

Stefan Glimm  
Executive Director  
Flexible Packaging Europe

# European News

John Dixon

## Plastics Implementation Measure (PIM)

The PIM made its way into law as the “*Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food*”. It came into effect on May 1, 2011.

Previous editions of this newsletter have dealt with the changes contained in this legislation. However, points to stress include:

- Materials and articles that were lawful under the old legislation before May 1 can continue to be put on the market until the end of 2012.
- Although the Regulation introduces new rules for migration testing, the old rules will apply until the end of 2012.
- Either the old or the new rules can be used for the next three years.
- From the start of 2016, only the new rules apply.
- The Guidance Document to aid compliance with the new Regulation is behind schedule and intentions are to publish some parts of the document by the end of the year. Other parts, e.g. those on testing, are unlikely to come out until 2013.

The first amendment to the Regulation, banning the use of bisphenol A in baby’s feeding bottles, was enacted almost immediately.

The second amendment, largely concerned with additions and amendments to the Union list of substances, is being prepared. A third amendment, dealing with changes to the text, is expected by the end of the year.

## GMP and DoC

To reflect the changes in the new legislation, FPE has updated two documents. The Code for Good Manufacturing Practice (Version 6.0) has rewritten sections on “Method” and “Design for Compliance”; additions to the section on “Migration”; and an additional section on Change Control”. FPE has also published a revised Template for the Declaration of Compliance containing all the new legislative references.

## Council of Europe Resolution on Metals and Alloys in Contact with Food

The Joint Expert Committee on Food Additives (JECFA) is an international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization. In 2006, JECFA reassessed aluminium and introduced a new Provisional Tolerable Weekly Intake (PTWI) of 1 mg/kg body weight/week. In their draft Resolution, the Council of Europe (CoE) used this PTWI to generate a Specific Release Limit for aluminium of 0.9 mg/kg food.

In many cases where salty or acidic foods are packed in contact with uncoated aluminium, this limit is likely to be exceeded. For lacquered aluminium, the possibility is that some applications would not be compliant – or at least very close to the limit. Where a continuous layer of polymer, e.g. polyethylene, separates the aluminium from the food, it acts as a functional barrier and there should be no problems meeting the limit.

Faced with this threat to some of our products, FPE and member companies have been active in supporting the European Aluminium Association (EAA) in making submissions to the CoE for the limit to be raised to 5 mg/kg food.

Arguments included:

- Of our total exposure to aluminium, the CoE allocated 10% to the release from materials and articles in contact with food. This allocation should be raised to 20%.
- The CoE assumed that people eat 1 kg of food per day packed in aluminium; the real exposure is much lower.
- Certain applications involving plain foil would have difficulty complying even with 5 mg/kg while posing no threat to human health. Higher limits should be allowed under the ALARA principle (As Low As Reasonably Achievable).

Additionally, EAA argue strongly that no limits should be set until a testing methodology is agreed. Testing for low levels of aluminium in food is complex and difficult, partly because of

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variable rates of extraction from the food, partly because of variable natural levels of aluminium already present in the food.

These arguments, presented to the CoE at the end of June, will be considered when they meet again in the autumn. Meanwhile, we learn that, following representation from the aluminium industry, JECFA have increased the PTWI to 2 mg/kg body weight/week, which should at least result in a doubling of the Specific Release Limit.

While the CoE Resolution has no legal standing, there is no other EU legislation on this issue. Consequently there is every chance that national authorities adopt the provisions of the Resolution and it could become a *de facto* standard.

## Non Plastic Food Contact Materials

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An EFSA Scientific Cooperation Working Group was set up in February 2010 to look at the substances in non-plastic food contact materials for which, in general, there is no harmonised legislation. Information present at Member State level was collected and an inventory made of some 3,000 substances, some of which were evaluated before the “modern” SCF Guidelines were drawn up in 1991.

In its report published in July, the Working Group make proposals on prioritising risk assessments and dealing with emergency situations. They recommend the use of tools such as the Threshold of Toxicological Concern and FACET. They have also set up a “network of experts” from national authorities and industry that can be mobilised in times of crisis.

The EU Commission has also said that it will publish a “road map” for regulation of these non-plastics. A necessary first step would be an impact assessment for such regulation, e.g. the economic consequences. Since such assessments can take up to two years, it is clear that we cannot expect anything in the very near future.

## Sensory Test Methods

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A workshop on sensory testing is planned by the European Union Reference Laboratory for food contact materials. An important clause in Article 3 of the Framework regulation requires that packaging should not adversely affect the taste of the food, yet there is a lack of guidance on methodologies to demonstrate compliance.

FPE plans to send delegates from member companies to this workshop and expects that they will be able to make a valuable contribution.

This is an important subject from the commercial as well as regulatory point of view. As an example, in March this year, Kellogg’s in the United States launched a multi-million dollar lawsuit against a Canadian converter, FPC Flexible Packaging Corp. They claim that microcrystalline wax used in the manufacturer of cereal liners was contaminated by hydrocarbons (methylnaphthalene?), causing the national recall of four brands.

In counterclaim, FPC is demanding payment by Kellogg’s for \$4.5 million worth of materials supplied and stock held.

## Cores

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The “Article 21 Committee” decides what should and should not be defined as packaging in terms of the Packaging and Packaging Waste Directive. In March this year, they re-opened the issue of cores, proposing that they should be classified as packaging.

FPE joined with other organisations in saying that the cores used for flexible packaging are an essential part of an industrial process and cannot be regarded as packaging in the same way as household rolls of paper and aluminium foil. So far, these efforts have met with some success in that the Committee has been unable to achieve the required majority vote and must return with revised proposals.

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# National News

John Dixon

## Swiss Ordinance

The 3rd edition of Annex 6 to the Swiss Ordinance came into force on May 1, 2011. This contains the List A of evaluated substances with Specific Migration Limits if appropriate, and List B of unevaluated substances where a 10 ppb limit applies.

There has been some movement of substances from List B to List A but there are still issues. In particular, FPE had identified certain important solvents, which were and still are, missing from List A. These are hydrocarbons, mainly used in coldseal release lacquers, and some oxygenated solvents, e.g. ethoxypropanol, mainly used as retarders. For the hydrocarbons, there is a plan for the European Solvents Industry Group to present REACH based dossiers to the Swiss authorities.

It is hoped that these dossiers will allow their transfer to List A. However, there seems to have been little progress on the oxygenated solvents and FPE members have been asked to put direct pressure on their solvent suppliers for action.

## German Ordinance on Printing Inks

As expected, the German Ministry of Food, Agriculture and Consumer Protection submitted a first draft of the German Ordinance on Printing Inks in early January 2011. It included:

- A positive list for substances in inks which have been evaluated – loosely corresponding to the Swiss List A
- An inventory list for non-evaluated substances with migration limit of 10 ppb in food – loosely corresponding to Swiss List B.
- A ban on nanomaterials unless specifically included as such in the positive list

Since it is unlikely that there will be EU regulation in the near future, there is every likelihood that the German Ordinance, if adopted, will become a de facto standard for the rest of Europe.

On April 11, 2011 there was a hearing with the German Authorities attended by all players in the supply chain from the ink manufacturers to the retailers, with GDA representing the interests of the flexible packaging converters. The main points at issue are:

- The definition of what is a printing ink and what is a coating (not subject to the Ordinance)

- The restrictions on nanomaterials, as defined in the draft Ordinance, which would exclude the use of most pigments.
- Whether the retailers or the substance and ink manufacturers should have the responsibility to submit substances for the inventory list.
- A transition period of perhaps one year to comply would be inadequate to assess the many substances currently used but not yet on the positive list.

A second draft is due towards the end of the summer.

## Belgian Legislation on Coatings

The Belgian authorities have recently drafted a proposed decree on coatings for food contact materials. This would apply to all coatings, whether in direct food contact or not. Loosely based on the CEPE Code of Practice (CoP) for coatings, there are important differences which would make it impossible for many coatings to comply in the near future:

- The CoP excludes coatings for flexibles and does not list the substances used in such coatings. Therefore the decree will be missing many substances.
- The decree requires a 10 ppb limit for unlisted substances. The CoP permits mutagenicity tests according to REACH timeframes to allow a 50 ppb limit.
- The decree requires compliance with Specific Migration Limits. The CoP allows for the possibility of using exposure assessments.

A Belgian based member has responded to the draft with these and other issues.

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# Substances in the News

John Dixon

## Bisphenol A (BPA)

From March 1, 2011 Bisphenol A (BPA) was banned in the EU from use in the manufacture of infant feeding bottles by an amendment to the Plastics Directive 2002/72. Following the repeal of the Directive, the ban was continued by Regulation 321/2011, the first amendment to the Plastics Regulation 10/2011. The marketing or selling of such bottles is outlawed from June 1, 2011.

There do not appear to be any immediate plans by the Commission to extend this ban to other packs. However in April 2011 two official Swedish agencies put forward proposals that would oblige food processors and packaging companies to submit plans by the end of the year on how they can substitute current can linings with BPA-free alternatives.

On the toxicological front, we still receive a number of conflicting reports. On the one hand, there are new papers claiming that human exposure to BPA has been underestimated, that BPA can affect behavioural patterns of deer mice and that foetal exposure is linked to lower birth weight and wheezing.

On the other hand, bodies such as the German Society of Toxicology and the UK's Committee on Toxicology continue to support the current Tolerable Daily Intake laid down by EFSA.

With little meeting of scientific minds on this issue, it seems likely that political pressure will continue to drive further restrictions on this substance, initially at a national level.

- Mineral oil aromatic hydrocarbons (MOAH) (C10-25): 0.15 mg/kg food (=DL)
- Mineral oil saturated hydrocarbons (MOSH) (C10-25): 0.6 mg/kg food

Carton printers have committed to use low migration inks as a first step to meeting these limits. However, it will be much more difficult to avoid the mineral oils that arise in recycled fibre, which mainly originate in the inks used to print newspapers. These are unlikely to be changed to more expensive, low migration grades. The use of 100% virgin fibre in board is unacceptable on grounds of costs, supply and environmental impact. So the carton industry is faced with a very real problem.

Although the flexible industry uses very little paper made with recycled fibre, this proposed Ordinance could still cause some issues. Hydrocarbons are difficult to analyse and characterise and other products which may be present in flexibles, e.g. polyolefin oligomers or components of waxes, could be mistakenly identified as mineral oils.

A further potential issue is that the concerns about mineral oils could widen to take in other hydrocarbons such as the oligomers. These are present in many of the polymers used and have the potential to migrate into foodstuffs. FPE is monitoring the situation carefully.

## French Deputies Pass Ban

In May, the French National Assembly passed a ban on phthalates, alkylphenols and parabens in consumer products. This move was not supported by the government and would need also to be passed by the Senate, where a vote is not likely until September 2011. The measure, as drafted, is very simplistic and unlikely to survive in its present form. However, it is an indication of the growing (sometimes ill informed) opinion against potential endocrine disruptors and we can expect further measures in the future.

## Mineral Hydrocarbons

Reported in the last issue were concerns that mineral oils, mainly originating in recycled board, could transfer into foodstuffs. Responding to these concerns, the German Ministry of Food, Agriculture and Consumer Protection drafted an Ordinance which would limit the migration of mineral oils from recycled paper and board into food to:

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