

Cooperation across growing flexible packaging sector brings major benefits

With the rise in consumption of packaged products offering a strong customer base for the global flexible packaging market, the past year has proved to be both exciting and challenging. According to a recent report published by MarketsandMarkets, the flexible packaging market is estimated to grow from \$73,825.3 million in 2012 to \$99,621.9 million by 2018. In terms of revenue in 2012 Asia-Pacific led the global market followed by North America and Europe.

The report identifies that Europe is growing at a CAGR of 3.9%, driven mainly by the East European markets and that in mature markets, such as North America and Europe, demand for specialty films is growing at a faster rate than conventional resin-based films.

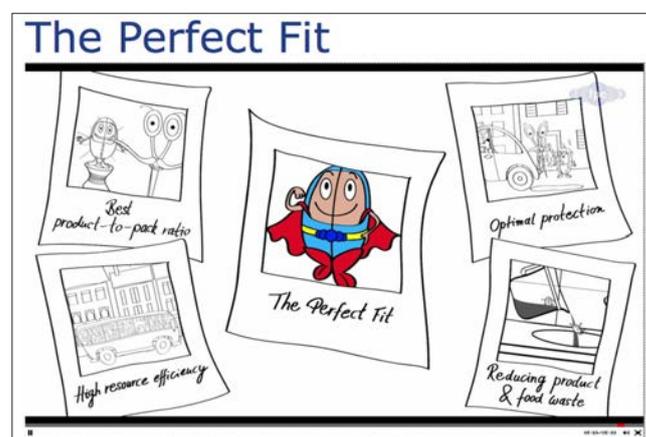
While this sets the scene for a competitive market it continues to be vital that we all benefit from increasing involvement with the association – to the advantage of the flexible packaging industry as a whole. So it is rewarding to see that members' participation in our activities is growing and, as a result, this is helping to position the complete sector as pro-active, focussed on addressing customer needs and the increasing legislative challenges.

Of particular note is FPE's Technical Committee, which has gone from strength to strength, with more than 20 companies and several associations working together on relevant and important food contact issues. The Technical Committee takes an active role in numerous projects to smooth and guide the legislative and regulatory process.

Only in close cooperation can we respond to important demands from the European Commission and from customers and their associations across the supply chain.

On the sustainability front, FPE's work on Life Cycle Assessment (LCA) – as a tool to demonstrate the positive contribution flexible packaging plays thanks to its resource efficiency to enable sustainable consumption – has been acknowledged by United Nations Environment Programme (UNEP). A number of LCAs undertaken by FPE have been included in this wide ranging, in depth, report to establish best practice in using LCA as an assessment tool for packaging.

The report, produced under the Life Cycle Initiative – a joint organisation of UNEP and the Society of Environmental Toxicology and Chemistry can be downloaded here. Executive summaries of the LCA studies referred to are available on the FPE website.



I am also pleased to announce FPE's sustainability work has had another boost with the animation of "The Perfect Fit". Available online, the animated film brings to life this Thought Leadership Paper. It shows how flexible packaging offers the 'perfect fit' solution to sustainability challenges today, providing a simple and adaptable answer to portioning, preservation and demands for convenience. The animation, as well as the report, can be viewed at www.flexpack-europe.org

Jan Homan
FPE Chairman



European News

Plastics Regulation

The 4th Amendment to the Plastics Regulation 10/2011 adds two substances to the Union list and makes some other amendments. Our understanding is that the text is finalised and publication can be expected in April 2014.

The 5th Amendment will make improvements to the text of 10/2011. These proposals are still under discussion. There may be significant changes in Article 15 as to who should provide a Declaration of Compliance (DoC) and who should receive a DoC. In particular:

- Should importers provide DoCs? The consensus is "Yes". They should be based on supporting documents provided by the manufacturer.
- Should small retailers, for example butchers who have their own packaging operation, receive DoCs? The consensus is "No". They do not have the expertise to interpret them. In addition labelling of the packaging, such as restrictions on conditions of use, is adequate.

Further changes to the legal text may come out of the discussions on the Guidance Documents. As previously reported, there are three documents being prepared by the Commission to give guidance on 10/2011. The document dealing with the Regulation in general is virtually complete. Another covers information in the supply chain, i.e. the DoC. In the discussions on this, FPE has been successful in gaining agreement that a single DoC can cover a range of products, for example:

- Different sizes
- Different prints or colours
- Batches made using alternative sources of supply – and hence possibly containing different SML substances

In the latter case, one can list all the possible substances that might be present, identifying those that are alternatives with an asterisk. We hope that these first two documents will be published early in 2014. However, the third document, which gives guidance on testing, is still being drafted by a committee of experts and may get further delayed by being put out to public consultation.

To reflect the new Guidance, a working group of FPE members has been revising our template for a model DoC. This will be published as soon as the Commission documents are finalised.

Council of Europe Resolution Metals and Alloys in Contact with Food

In July, the Council of Europe (CoE) adopted Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles. This was followed in October by publication of the

Technical Guide. It sets Specific Release Limits (SRLs) for 23 metal ions. These are the maximum permitted amounts which may be released from a material or article into a foodstuff or simulant. The limit for aluminium is 5 mg/kg food or simulant. The guide specifies experimental test methods for verifying compliance with the SRL and lists the information that should be contained in a declaration that a material or article complies with the Resolution.

Although the Resolution has no legal standing at the moment, it will probably be adopted as a method of demonstrating that a material complies with Article 3 of the Framework Regulation 1935/2004. In addition, Belgium has announced its intention of adopting the provisions into their national law and Germany and other States may well follow them.

The ease of compliance will depend on the type of structure:

- Uncoated aluminium in contact with acidic, alkali or salty foods may well release aluminium ions at levels which would not comply. Such materials and articles must be tested under appropriate conditions. If necessary, one must advise against the use for such foods, for example by labelling.
- Regular testing should not be needed where there is a layer of polyethylene or polypropylene in contact with the food. This should act as a functional barrier to the metal ions and prevent any release.
- Where an aluminium foil is coated with a lacquer or varnish, the effectiveness of such a coating will depend on factors such as its chemical nature, its thickness and its continuity, i.e. absence of pinholes. Therefore, members should test such structures to check for compliance.

Council of Europe Database

There has been no news on the EU "Roadmap" for the regulation of non-harmonised food contact materials. We must assume that the impact assessment of the various options is continuing. However, there do seem to be moves to use the CoE to control such material with revisions of the existing Resolutions, e.g. on coatings, inks and paper.

Linked to this is a proposal to maintain a database on substances in all food contact materials – both plastics and non-plastics. Belgium has created such a database which records actual toxicological data, existing restrictions and some end points from applying computer based tools to estimate the probable toxicity of non evaluated substances. They have a mandate to explore ways in which the database could be maintained, such as industry paying for access.

A number of FPE members have expressed an interest in subscribing to such a database. We must now see whether there is sufficient interest from industry as whole to make the project viable.

REACH

A key issue under REACH, which could affect the majority of FPE members, is the Authorisation of chromium (VI) compounds. These are carcinogenic and have been placed in Annex XIV of REACH. This means that, from 2016, they will be banned from use within the EU unless their use for specific processes has been Authorised.

At the moment, Cr (VI) is considered to be essential for the chrome plating of high quality rotogravure cylinders. Hence European cylinder production will effectively cease from 2016 unless the plating process is authorised. The European Rotogravure Association (ERA) is participating in the Consortium seeking Authorisation for this process. An important part of their submission will be a Socio-Economic Analysis which details the benefits of use of Cr (VI) and the consequences of a ban. A questionnaire for printers will provide some of the evidence for this analysis. FPE has offered its assistance to ERA in completing such questionnaires.

Solvent Emissions

A key publication used in the control of solvent emissions is the BREF – Best Available Techniques (BAT) Reference Document. There are 33 of these, each dealing with a different sector. Flexible packaging production comes under “Surface Treatment Using Organic Solvents”, as do other printing operations and activities such as painting and coating of cars, trains, metal packaging, furniture, etc. The BREF is a substantial document (722 pages) and contains:

- General information on printing and printing products and a description of processes and techniques
- Current solvent consumption and emission levels
- Techniques to be considered in the determination of BAT
- The Best Available Techniques - 46 of which are applicable to all industries. Others only apply to printing, including emission values as a percentage of reference emissions
- The methods for calculating or measuring parameters, e.g. reference and actual emissions and fugitive emissions

Our BREF was finalised in 2007 and it was not due for revision until 2016. This has now been brought forward to start in 2014 and will take some 2 years to complete. FPE will need to be involved in this process, probably working with other printing associations. There will be a need for input from members such as responding to questionnaires on emission levels and on abatement techniques.

National News

Swiss Ink Ordinance

A key issue for converters has been the presence on List B of a number of oxygenated solvents which are used as retarders. They are

therefore limited to 10 ppb in the food, a level which can be both difficult to achieve and to measure. Dossiers submitted by the European Solvents Industry Group (ESIG) had previously been rejected but we now understand that a revised model dossier has been accepted by the authorities for both form and content. Work is now underway to prepare dossiers on all 40 or so substances to enable them to be transferred to List A with reasonable migration limits.

German Ordinance on Printing Inks

The evaluation of these dossiers will be done jointly by the Swiss and German authorities. It is hoped that this will be completed in time for the substances also to be included in the German positive list. The timing on this may be tight since a fourth and probably final draft of their ink regulation has now been published. There is a very limited time for industry comments and any further changes will only be editorial. EU notification may be expected Q1 2014 and final passage through German legislative process by Q1 2015. Industry had asked for a three-year transition period but it will probably be just one year as previously announced. Hence the measure will apply from Q1 2016.

Other National Legislation

In February Belgium published a further draft of their Royal Decree on coatings for food contact. There are still a number of issues to be resolved, including the simulant and test method to be used for overall migration testing of aluminium based structures. It is not clear when the decree will be finalised.

The Netherlands has notified the Commission of amendments to their Warenwet. Most of the changes reflect changes in EU regulations. However, we have been told that there is a possibility of more far reaching changes in the future, including an adoption of the CEPE Code of Practice for food contact coatings.

Substances in the news

Bisphenol A (BPA)

The toxicological arguments on Bisphenol A (BPA) continue without any sign of consensus. EFSA have published a draft opinion on consumer exposure to BPA – which shows levels much lower than those previously estimated. Their full opinion on the potential human health risks is due in early 2014.

Meanwhile efforts to replace BPA based coatings continue. France has instituted a ban (technically a “suspension”) for the under 3s from 2013 and a total ban from 2015. They are also bringing in a requirement for all packaging containing BPA to include a warning label such as “Made using Bisphenol A. Use not recommended for pregnant or breast-feeding women or for children under three”. This labelling measure will probably come into force in April 2014 at the earliest.

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Substances in the news ... continued from previous page

The test methods and limits to be used in enforcement are not yet clear. It is certain that no BPA based coatings may be used on the food contact surface. However, it may be possible to use such coatings on the outside of a package provided that transfer of any residual BPA to the food contact layer is below the specified limit.

Mineral Oil Hydrocarbons

In May Germany published a second draft of legislation on mineral oils in packaging. This Ordinance will only regulate Mineral Oil Aromatic Hydrocarbons (MOAH) and will only apply to recycled

fibre-based packaging immediately in contact with food, hence excluding transport packaging and virgin fibre-based packaging. It requires "no migration of MOAH of chain length 10 – 25 C" to food. However, no detection limit is set in the ordinance, neither is there a definition of MOAH. It assumes that "in general, according to the state of technology, a functional barrier would be required to avoid such migration".

In the pre-retailer supply chain it requires labelling of secondary packaging, unless it is not possible for any migration to take place. The labelling should explicitly refer to the obligation of the user to make sure that there is no migration to food of MOAH.

Research

Non Intentionally Added Substances

Non Intentionally Added Substances (NIAS) may be present in food contact materials:

- as impurities in raw materials
- as by-products from the reactions used to make materials
- or as the result of interactions between two different components of a structure

NIAS should be assessed for compliance with Article 3 of the Framework Regulation 1935/2004. Given the complexity and variety of flexible packaging structures, such assessments can place a considerable burden on the converter.

Since companies have many raw materials and processes in common, FPE set up a small Working Group to see whether there was any way in which information on these NIAS could be shared between members. This information could be at three levels:

1. Identification of the NIAS – sharing GC/MS data
2. Allocating the NIAS – identifying its source by sharing information on the structures and materials in which it is found
3. Risk assessment of the NIAS – sharing toxicological data

Dr Rainer Brandsch, who has considerable experience in this field, was approached and he has made a proposal for a database to hold such information. The running costs would be met by subscriptions

from companies wishing to have access. A system of credits would be used to encourage companies to contribute their screening results.

At the time of writing, it is not certain whether there is sufficient support for this project to make it commercially viable. However, it is clear that the issue of NIAS will assume more and more importance in the coming years.

FACET

Over the last few months the FACET exposure modelling tool has undergone several rounds of testing, modification and re-testing. In a basic form – running 5 pre-loaded substances for which the base data has been checked – the model seems to work well. However, there are probably too many gaps in the base data for it to be reliable on other substances. Such gaps could be filled but it would require a second round of data gathering from industry. As a "proof of principle" pilot project, FACET has been a success. As a complete project, capable of covering all substances, its reliability is more questionable.

There remains the possibility of developing a more advanced model which could be used to estimate exposure from user defined substances which are present at user defined occurrences/ concentrations in specific materials. Such a capability would not rely on the existing base data and could be very useful to FPE members, for example in the estimating of exposure to NIAS.

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