

Technical Committee – provides FPE's backbone in a legislative atmosphere

In a pro-active response to the growing legislative, regulatory and technical requirements which the flexible packaging sector is facing, Flexible Packaging Europe has further enhanced its Technical Committee with the appointment of Robert Broughton, Product Safety Manager – Amcor Flexibles Europe and Americas, as Chairman; and Dr Martin Kornfeld, Head of R&D, Constantia Flexibles, as Vice-Chairman.

"Many challenges are being faced by our sector including food contact compliance issues which for several years has been the most significant issue for FPE," says Robert Broughton.

"The fundamental changes with the Plastics Implementation Measure (PIM), which sets out to place into one regulation all rules on plastic materials in contact with food, must be closely monitored by the Technical Committee and members kept up-to-date with all compliance issues. An abundance of information

with explanation, including guidelines and supporting documentation will need to be distributed to FPE's membership." The impact of the 7th Amendment to the Plastic Directive will also need to be monitored.

Equally essential is the ability to guide the legislative process in Brussels where the Technical Committee has an efficient lobbying team that keeps FPE abreast of upcoming legislation and its possible impact.

This ensures that the association can positively affect future legislation to the benefit of the complete supply chain and the consumer.

For example, independent investigative work on food contact compliance has been commissioned by the Technical Committee to demonstrate the advantages offered by flexible packaging materials. The analytical studies will be used to produce case studies on functional barriers for various types of material structures and what these barriers offer across a range of different substrates in terms of migration and the extent of the functional barrier performance needed for specific time scales. Publication is expected in mid 2011.

It is also critical to ensure that all direct and indirect parts of the flexible packaging sector work together, explained Broughton: "There have been a number of well-publicised cases involving migration issues in recent years and working with associations that represent other materials and products used in flexible packaging is an important remit for the committee."

FPE has, for example, worked closely with CEFIC (chemicals), CEPI (paper and board manufacturers), and CITPA (paper and board converters), and in close co-operation with the latter has

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Creating understanding

Robert Broughton thanks all FPE member companies that provide the lead experts for the Technical Committee. He also calls for support and information from all FPE members and individual experts. "We are always open to comments and help from our membership. Only by working closely together can the Technical Committee create an understanding of flexible packaging to the benefit of all involved in our industry."



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published a "Code for Good Manufacturing Practices for Flexible and Fibre-based Packaging for Food" which is available for download from the FPE web site: www.flexpack-europe.org

The Committee is also working with the complete plastic supply chain, ink suppliers and their associations to create a strong and effective partnership. "An excellent example of the type of co-operation that can be reached is the Packaging Ink Joint Industry Task Force through which FPE and other associations have joined together to raise concerns with the Swiss Government about compliance with the new Swiss Ordinance on Packaging Inks, which gives lists of the substances permitted for use in inks. The list has some notable omissions and is creating problems for packaging inks; clarification is needed urgently," said Broughton.

FPE's Technical Committee takes an active role in numerous projects to smooth and guide the legislative and regulatory process. Just a few examples include its major role in FACET (an EU project which aims to use exposure as a tool for use in future food contact legislation). e.g. agreeing common codes for

foods and packaging materials, supplying flexible packaging material usage data; REACH regulations; hygiene and food safety; Good Manufacturing Practice and the proposals for EN standards and many more projects.

"The extension of the Technical Committee and its specialist working groups will assist FPE members and the supply chain to stay abreast of all issues that affect our industries through the efficient dissemination of news and technical information, as they impact on converters, suppliers and user industries."

- Robert Broughton

News from Brussels

John Dixon

Plastics Implementation Measure (PIM)

This important measure replaces and updates a number of Directives dealing with plastic materials and articles intended to come into contact with food. The most important changes are summarised below.

The existing Plastic Directive applies only to all plastic materials, but importantly the PIM requires that the plastic components of both plastic multi-layers and multi-material multi-layers may be made only from the "Union List" of authorised substances. This list includes starting substances (e.g. monomers), additives (but not colourants) and Polymer Production Aids. Additives that were petitioned to the European Food Safety Authority (EFSA) before January 1, 2007 and which are on the "Provisional List" may continue to be used pending a decision on their inclusion in the Union List. Unlisted Polymer Production Aids may also continue to be used subject to national regulations.

Plastic multi-layers must comply with the Overall Migration Limit of 10 mg/dm². Some listed substances are subject to Specific Migration Limits and must not transfer to the food in quantities

exceeding the limit. There are new and separate rules for assessing compliance to both types of limit. These specify the simulants, and time and temperature of contact to be used. Note that a new simulant, modified polyphenylene oxide ('Tenax') has been introduced for dry foods.

The plastic components in multi-material multi-layers must also respect the compositional requirements. However, they do not have to meet the OML or SML.

Inks, coatings and adhesives in plastic multi-layers may be manufactured using unlisted substances. However, if they contain any listed substances that are subject to an SML, this limit must be met.

Other Provisions

These cover restrictions on substances in nanoform, the concept of a functional barrier and the possibility of using migration modelling and other strategies in place of actual

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testing when screening materials. The Regulation specifies the content of the written Declaration of Compliance, confirming that the material complies with the rules. This is to be made available to the customer. Supporting documentation must be kept and, on request, made available to the authorities.

A Technical Guidance Document is being prepared which will give further guidance on the DoC and other aspects of the Regulation. FPE members have made important contributions to this document, however, the Commission has delayed work on it and it may not be ready for some time.

The PIM is expected to be published early in 2011 and to apply from May 1 2011.

There are a number of transitional provisions:

- Products which comply with existing legislation are permitted to be placed on the market until the end of 2012;
- Existing migration testing rules should also be used until this date for DoCs and to demonstrate compliance;
- For 2013 to the end of 2015, either the old or the new rules may be used.
- From 2016, only the new rules are valid.

Good Manufacturing Practice (GMP)

The new Regulation means that there will be a need to update FPE's Guidelines for GMP and for the content of DoCs. A working group of the FPE Technical Committee will meet in 2011 to agree a revised version.

Packaging Ink Joint Industry Task Force (PIJITF)

The forum, which brings together representatives from food manufacturers, packaging converters and ink suppliers, continues to address the issues created by the Swiss Ordinance (SR 817.023.21). It has two categories of starting substances for inks, "List A", for those which have been fully evaluated, and "List B", for those which have not. The latter are to be non-detectable at a level of less than 10 ppb. Given the huge numbers (about 4,000) in List B and the slow rate of evaluation, it is desirable to prioritise the substances for removal from B to A.

The European Printing Ink Association (EuPIA) has identified 10

to 15 such substances. FPE is asking its members to help identify any important solvents which should be moved to List A. Contact is being made with the European Solvents Industry Group requesting the necessary toxicological information. Other substances which will be prioritised include acrylates, photoinitiators and adhesion promoters.

In many cases, it is not possible for converters to demonstrate compliance with the ordinance. The Swiss Federal Office of Public Health (FOPH) appear to be sympathetic to the issue and it is hoped to produce a joint FOPH/ PIJITF document on compliance procedures, probably in the form of 'Frequently Asked Questions' and answers.

Proposed German Regulations on inks

The German Ministry of Food, Agriculture and Consumer Protection plans to issue a regulation on printing inks for food packaging. No details have yet been published but it is thought that it will follow the form of the Swiss regulation. Whereas the List A of the latter contains substances that have been evaluated by industry, it is possible that the German equivalent will contain only officially evaluated substances.

Publication of a draft text is awaited with interest.

Non Plastic Food Contact Materials

Over the past year, an EFSA panel has been looking into the safety of non-plastic materials used in food contact packaging. It has been examining information that is currently available, how to set priorities for future evaluations and future actions that should be taken. The panel is likely to concentrate on printing inks and paper & board.

A workshop will be held in March 2011 to report on its findings and gather feedback from a wider audience.

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Substances in the news

Bisphenol A (BPA)

The arguments on the safety of BPA continue. In July, the Joint Research Centre of the European Union published a report highlighting the fundamental divide in scientific opinion.

There are a number of reports claiming ill effects from exposure to even very low doses of BPA. However, the Joint Research Centre claims that most of these studies did not follow international guidelines and were not in compliance with Good Laboratory Practice. Moreover, when experiments were repeated following the guidelines and practice, the results could not be reproduced. In counter argument, there have been claims that the guidelines studies are themselves based on out-of-date protocols and are inadequate.

In September, the European Food Safety Authority published its latest opinion. It said it would maintain the Tolerable Daily Intake of 0.05 mg/kg bodyweight/day, originally set in 2006 and confirmed in 2008. EFSA considered a recent neurodevelopmental report "inconclusive" and said that adverse effects reported in other studies were not "clearly reproducible".

However, the European Commission decided that this opinion also raised "uncertainties" and member states have agreed a ban on BPA in polycarbonate feeding bottles for babies. This will be implemented by an amendment to the Plastics Directive 2002/72 and will come into full force from June 2011. The Commission says that there are "no plans" to extend the ban to other materials such as can linings or coatings for flexibles. Even if this is so, it is anticipated that there will be continued business to business pressure to reduce or eliminate BPA use in food packaging.

All FPE members, including those not directly affected, should continue to be concerned at the way this issue has developed. The use of BPA has been restricted despite the EFSA opinion. Both FPE and its customers must have confidence in EFSA if they are to rely on its toxicological and risk assessment expertise and not be forced into reacting to every media scare or "substance of the month". The Commission's action may reduce confidence and make it harder to resist unnecessary changes – possibly the use of materials containing substances that have not been so well studied.

Mineral Oils

Although of principle concern to the carton industry, flexible packaging manufacturers should be aware that a number of studies have raised concerns over the presence of mineral oils in cartons in contact with food and potential transfer into the food.

These substances contain mixes of saturated and aromatic

hydrocarbons with a range of chain lengths. This makes it difficult both to analyse them and to carry out risk assessments. However the German Federal Institute for Risk Assessment recommends that the exposure of the consumer to these substances should be minimised.

Some surveys have shown their presence in food contact cartons made from both virgin and recycled materials. In the former case, the most likely source is the use of unsuitable, offset printing inks containing mineral oil. The solution is for printers to follow the recommendations of the EuPIA which are to use only low migration inks, formulated without mineral oils, for food packaging.

In the case of cartons made with recycled fibre, the source of the mineral oil is mainly non-food grade inks (e.g. those used for printing newspapers) which are not completely removed by the recycling process and may persist in the recycled paper and board. A number of strategies have been discussed, including:

- Using only virgin fibre for food grade cartonboard – probably unacceptable if recycling rates are to be maintained;
- Reformulating newspaper ink to be free of mineral oil. This has the advantage of reduced the consumer exposure through skin absorption;
- Using a barrier flexible liner within the carton – a business opportunity for FPE members if hardly a reduction in packaging usage!

Contamination

Contamination of packaging and hence of the food through migration should remain an on-going concern. Avoidance of contamination relies on the consistent application of GMP throughout the supply chain. In some ways, it can be more difficult to manage than the safety of substances that are deliberately used in formulations.

This is illustrated by research in the United States which was originally aimed at estimating the environmental levels of polybrominated diphenyl ether (PBDE), a flame retardant for electronic and textiles, which is being phased out because of its toxicity. During the survey, the researchers found a particular sample of butter that gave PBDE levels more than 100 times that of the others. Since the level of the chemical in the paper wrapper was 16 times that in the butter, the researchers concluded that the packaging was the "most likely" source of the contamination, possibly from electronic devices used in the converting plant or paper mill. If it were the mill, one can imagine the difficulty the converter might have tracing and proving the source of the contamination.

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However, an alternative explanation was proposed by the US National Wooden Pallet and Container Association which issued a news release with the demand that "given the high levels of PBDE used in plastic pallets, they should be examined as the root source of transfer to the food".

In response, pallet manufacturers filed a lawsuit alleging that such statements were "false, malicious and defamatory". This 'fight' acts as a reminder that both plastic and wooden pallets

are potential sources of contamination for flexible packaging materials. In the past, there have been several cases of chemicals migrating from pallets into reels of packaging causing off odours. Unless there is a barrier layer under the reels, the chemical specification of pallets must be controlled.

Research activity

John Dixon

FACET

The FACET project is now more than halfway through its four year life. Broadly speaking, it is progressing to plan. FPE's role in the project has been to provide layer by layer descriptions of the flexible packaging structures used for different foodstuffs. Members have provided information on the type and thickness of the materials used to make these structures.

This data has been collated and made anonymous by FPE's consultant. A first version of the collated data was completed in May 2010 and was used to help develop initial versions of the exposure assessment software. Subsequently, some FPE members were able to provide additional figures and a second, final version of the collated data was completed in October 2010.

Twenty companies contributed more than 13,000 lines of information with each line representing a different food/ structure combination. FPE's Technical Committee is aware of the effort that went into providing this data and would like to take this opportunity to thank everyone who contributed. The quality and detail of the data is generally excellent and will enable a second version to be supplied to the software developers at the end of 2011. Special thanks are also due to the members of the FPE FACET Task Force whose efforts, particularly at the early stages of the project, were key to success.

There has been some analysis to try to determine how representative the figures are compared with the European market as a whole. As one might expect, it would seem that FPE members are very strong in the more complex, printed structures supplied for manufactured foods and FPE has a high level of confidence that its data reflects actual usage accurately. However, it is also clear that members are much weaker in the supply of unprinted packaging in general and in particular structures for packing fresh foods, e.g. meat, fruit and vegetables. The FACET project will need to ask other trade associations for input to complement FPE's data in these areas.

FPE's data gathering role is now largely complete but it will continue to play an active role in FACET to ensure that the project results in a useful tool. In addition to participating in the FACET Industry Group, discussions will continue with other trade associations. The association needs to be certain that the chemical substances in members' raw materials, particularly for inks and adhesives, are properly described. There are areas where the product range for flexible packaging materials overlaps with other packaging producer organisations (e.g. paper and board) and these issues need to be resolved. Last, but not least, we need to ensure that the final software tool performs as required and protects the confidentiality of the FPE data.

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