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FlexAffairs

Flexible Packaging Europe Newsletter

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A passionate approach to FPE and its Technical Committee

When Flexible Packaging Europe (FPE) was founded in 1989 (under the name Euroflex), to represent the flexible packaging industry at a European level, it could not have been known just how the work of the association would grow and develop to serve the needs of its members especially in the area of legislation and regulations affecting the industry. This sentiment is strongly held by the new chairman of FPE's Technical Committee, Dr Martin Kornfeld.

"I am passionate about FPE and even more passionate about the work the Technical Committee does," commented Dr Kornfeld. "Without the dedication and team work provided by the Technical Committee we would not be in as strong a position when it comes to guiding our members through the sheer volume and complexities of EU legislation and regulations."

> *As one of the main proponents of the FPE Technical Committee, Dr Kornfeld believes the value that is being created for the industry and the individual companies is very high.*

"The reason for it is clear and can be seen through FPE's initiatives past and present, says Dr Kornfeld. "We have been working continuously in the areas of PIM - food contact; REACH and projects such as FACET. We are lobbying on legislative issues and working with associations that represent other materials and products used in flexible packaging. Case studies have been done on functional barriers, migration and the extent of the functional barrier performance."

The Technical Committee keeps FPE and its members abreast of upcoming legislation and its possible impact. Providing news, regulatory and technical information, and how it may impact on converters, suppliers and user industries. Members are kept up-to-date with all compliance issues and are supplied with explanatory information, including guidelines and supporting documentation.

When discussing the forthcoming year Dr Kornfeld identified two main issues: Firstly, the individual approaches of European countries for regulating raw materials which are not regulated by the community. In addition to this, the diverse regulatory situation worldwide which basically poses huge problems for all who supply to globally acting companies in the food business. How to deal with this global aspect is an enormous challenge in itself. Now that the European Commission is considering extending the scope of harmonised regulation, FPE will have an important role to play in encouraging and influencing such moves."

Secondly, NIAS (Non Intentionally Added Substances). They will be discussed more and more in the forthcoming year. By definition, Dr Kornfeld explained, they are not intentionally added and cannot be totally eliminated. However, analytical capabilities and methods show a rapid advancement and risk assessment methods for NIAS will come more into the focus.

Commenting on his plans and aims for 2013 Dr Kornfeld says, "Basically, I think that an aligned position has to be worked out. We need to anticipate what the EU authorities will be focusing on and work constantly towards harmonised legislation."

Dr Martin Kornfeld,
Chairman
Technical Committee

Dr Kornfeld has worked for Constantia Flexibles for 16 years and the last 9 years has seen him heading Constantia Flexibles' major R&D facilities located at Constantia Teich which now constitutes Constantia Flexibles' R&D Competence Centre "Aluminium and Functional Coatings". The R&D Competence Centre's main focus is to develop foil-containing structures, and selected foil-free structures; and to develop and implement any kind of coating regardless of the substrate. In addition to this, the Competence Centre has the group-wide steering function for Regulatory Affairs for food contact materials and product sustainability.

European News

Plastics Regulation

The 3rd Amendment to the Plastic Regulation 10/2011 adds a few substances to the Union list of monomers, other starting substances and additives which may be used in the manufacture of plastic materials and articles. It also corrects some errors and makes some clarifications. It came into force January 1st 2013.

Over the last few months, there has been significant progress on the preparation of Guidance Notes for the Plastics Regulation. These notes will probably be published in three parts. The first will deal with definitions and a general explanation of the Regulation. It is hoped that this will be published early in 2013.

The second part deals with the Declaration of Compliance. It defines the various roles within the supply chain and describes the precise information that must be provided by companies in each of these roles. For example, the obligations of a supplier of polymer resins for food contact use are different from those of a supplier of the final materials and articles for packing the food. This document is also well advanced and publication should take place by mid-year.

The third part will deal with testing for compliance. There has been an initial meeting of the working group, many of whose members are analytical experts who will decide on the best test methods. FPE is represented and we shall be seeking to ensure that the guidance does not place an undue burden on our members. To this end we will seek to gain an official acceptance for practical techniques described in our "Code for GMP" such as the "Building Blocks" concept and the "Family Approach".

Future Approach for Non-Harmonised Food Contact Materials

At present, the EU has specific, harmonised measures for plastics, cello and ceramics. Other materials such as paper, aluminium, inks, adhesives, coatings are only covered by the general requirements of the Framework and GMP Regulations. In October, the Commission published a "Roadmap" in which they laid out some broad options for their future regulation.

Through 2013, a consultant will carry out an impact assessment of the various options, concentrating on their economic costs but also considering issues such their impact on SMEs and on the operation of the single market.

The Commission has also issued detailed questionnaires to trade associations seeking their views on both the present state of affairs and on future options.

Broadly speaking, there are three options:

1 Do nothing and leave it to the Member States to set up requirements at national level. This could be quick and cheap (for the Commission) but risks having either gaps or multiple regulations for a material and would entail higher costs for the converter.

2 Regulate at EU level, e.g. with positive lists and migration limits (like plastics) or with negative lists. This would be much easier both for industry to comply with one rule and for the authorities to control. There are known models to work from such as the US FDA Regulations and the Plastics Regulation. On the other hand, the new substance evaluations needed could be costly to industry and EFSA and it could take a long time to implement regulations for all materials.

3 Set out obligations and criteria for industry to do its own self assessments as well as bodies such as EFSA. This approach could be implemented quicker and would encourage innovation and the use of new risk assessment tools. However, it might be more difficult for the Member States to control and the necessary expertise might be a barrier for SMEs. There is also a potential for duplication of work.

FPE has set up a small working group to guide our views on future legislation. We believe that industry needs to work together to present the Commission with a unified view and that FPE needs to be part of that process. As consumers of many different types of material, we need rules that are as standard as possible. Whatever regulatory model emerges, high quality communication throughout the supply chain is absolutely essential. Compliance should be established as high up the supply chain as possible; we, the converters, should not be left "holding the baby". In summary, we wish to achieve legal compliance but with minimum costs to FPE members.

Council of Europe Resolution Metals and Alloys in Contact with Food

We can expect this Resolution to be published in the near future but the Technical Documents which form part of it are still under discussion. Test methods for measuring concentrations of aluminium in food and simulants have been agreed. It has also been agreed to specify the use of artificial tap water as a simulant for aqueous, alcoholic or fatty food and 5 g/L citric acid for acidic foods (pH ≤4.5).

However, the Specific Release Limits (SRL) have not been finalised. The latest draft sets a general SRL for aluminium of 5 mg/kg. This should be achievable for almost all lacquered structures. By exception, for household foil, barbecue trays and ready meal containers, up to 7 mg/kg is allowed.

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The 7 mg/kg exception may get dropped. In any case, even this higher limit may well be exceeded for unlacquered foil when it is in direct contact with acidic or salty food. As at present, unlacquered foil and containers will need to be labelled to advise against such use.

It is not clear what Member States, if any, will incorporate this Resolution into their national legislation. However, we can imagine that it will soon become a de facto European wide reference.

Biocides

Regulation (EU) no 528/2012 on biocidal products comes into force in September 2013, replacing Directive 98/8/EC. As something new, it introduces the concept of "treated articles". These are defined as "... any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products". Thus, in our industry, we would expect a water based coating, as delivered to the converter, which contains a biocide to extend its shelf life in the can to be classified as a "treated article". Similarly, a paper, e.g. for wrapping soap, that contained a fungicide to stop it going mouldy would also be one.

The Regulation imposes some requirements on such articles such as the active substance having to be listed for that particular application, the supplier having to respond within 45 days to consumer requests for information on the biocide and, under some circumstances, the product having to be labelled with information on the biocide. As such, we would have expected the Regulation to affect some of our suppliers but have little impact on the converter.

However, it now looks as if some Member States are trying to widen the definition to include anything that incorporated a "treated article" further up the supply chain. Thus a bar of chocolate, wrapped in packaging containing a coldseal which incorporated a biocide in its wet state, would also be considered a "treated article". So for that matter would be houses that were painted with water based emulsions! Our view is that such an interpretation is ridiculous since the converter does not "intentionally" incorporate the biocide. This view is shared by a number of other Member States. There is a working group preparing guidance documents to clarify the situation and FPE is making an input to this discussion, both directly to some Member States and through our membership of CheMI.

REACH

Under REACH, the most hazardous substances are controlled by being placed in Annex XIV of the Regulation. They then need to be specifically "Authorized" for each application. There is a process with a number of stages of assessment and evaluation before a substances is added to Annex XIV; the number of substances entering this process continues to grow. We inform members of this by circulating lists; more and more components of our raw materials are appearing in them. Being on a list does not mean that the use of a substance is inevitably going to be restricted or banned but, at the very least, it raises a question mark. Members would be wise to check with their suppliers the likely impact of any future restrictions.

A group of Chromium (VI) compounds are already in the final stages of being entered into Annex XIV. There will be a "sunset date" of May 2016, after which the substances cannot be used without authorization. These Cr (VI) compounds are currently considered to be essential for the production of high quality rotogravure cylinders. Of course, there are many other products which rely on chrome plating and a consortium has been set up to do the research and collect the data needed for the authorisation process. The cylinder industry is part of this consortium. Again, members would be wise to ensure that their suppliers keep them updated on the progress of the authorisation process and the development of alternatives to Cr (VI).

National News

Swiss Ink **Ordinance**

In the summer, FPE published a document, "Q&A on the Swiss Ordinance on Packaging Inks". This had been approved by the Packaging Inks Joint Industry Task Force, a group which covers the supply chain of ink manufacturers, packaging converters and food manufacturers. It can be downloaded from our website.

A number of oxygenated solvents, which may be used as retarders, are still missing from List A. The European Solvents Industry Group (ESIG) submitted dossiers on these products but they were not accepted. The reason is not clear; the Swiss and German authorities are reported to be working very closely together on their ink regulations and it may be that things are held up while the German authorities decide exactly what their procedures should be for evaluating and listing substances.

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German Ordinance **on Printing Inks**

There has been little activity on the proposed German Ordinance over the last six months, mainly because the official responsible left the Ministry and his successor has needed time to get "up to speed". The VdL (German ink makers) have submitted a list of the components of inks intended for direct food contact and ESIG have submitted dossiers on some solvents to the BfR. However, the dossiers have not been accepted. It is believed that the BfR is asking for more data on toxicology and migration. As in Switzerland, it is not clear exactly what is required.

The VdL and BLL (food manufacturers) have also contacted the Economics Ministry, pressing for regulation that is harmonised throughout the EU. If they find sympathy on this, it might lead to the whole initiative being stopped.

Belgian Legislation **on Coatings**

A further draft of the regulation was published in June with an annex that has largely been copied from the Plastics Regulation. It is now clear that the legislation will only apply to coatings in direct food contact. There will be a web based substance list and substances that have been authorised by national authorities such as FDA will be allowed. The new draft recognises that 3% acetic acid is not an appropriate simulant for foil based structures but does not suggest alternatives. It is not known when the regulation will be finalised and become law.

Substances in the News

Bisphenol A **(BPA)**

While the scientific claims and counter claims on the effects of Bisphenol A (BPA) continue and while we await a further EFSA opinion in May 2013, there have been moves at national level. We reported in the last issue how the French National Assembly had adopted a proposition which would suspend the use of food contact packaging containing BPA. Due to the Presidential election, this measure did not progress into law. However, the process was restarted in September and, following votes in the National Assembly and Senate and with support from the Government, there will be a general ban on BPA in food packaging from June 2015 with a prohibition for the under 3s starting immediately.

Last year, Denmark had already banned the use of BPA in packaging for foods intended for infants and young children. Belgium and Sweden have now introduced similar bans, starting from the 1st January 2013.

Mineral Oil **Hydrocarbons**

EFSA published their Opinion on Mineral Oil Hydrocarbons (MOH) in June. It identifies packaging made from recycled board as a major source of MOH in food – along with food additives, processing aids and lubricants. They conclude that the levels of exposure to MOH are of potential concern and warrant revision of the Acceptable Daily Intake for certain classes of mineral oils. However, there are no recommendations to lower the existing SMLs for low melting point waxes. Indeed, the European Wax Federation think that there are some things in the report which might justify an increase in the SMLs.

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