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FlexAffairs

Flexible Packaging Europe Newsletter

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Bridge to the future

The role of FPE

Is it coincidence or is it the nature of a healthy, growing and an increasingly European industry that the two 'giant' associations of the flexible packaging sector will become one in 2010?

FEDES – the traditional association for small- and medium-sized flexible packaging manufacturers - was dissolved at the end of 2009 to be integrated with Flexible Packaging Europe (FPE) to form an integrated and focussed voice for flexible packaging companies.

FlexAffairs our new newsletter replaces FEDES/FPE 'Monitor' and will update readers regularly on the latest developments about food contact legislation and sustainability.

Furthermore, we want to increase the active participation of existing and new members of FPE. We are sure that our services, which include benchmarking as the basis for continuous improvement, food contact and sustainability issues, will be of great interest and value to our members.

As consolidation of the flexible packaging industry continues it will become even more important to bridge the expectations of both the market leaders and medium-sized, often privately-owned, companies to position the complete sector as a pro-active entity focussed on customer demands and the increasing legislative burden.

Only in close cooperation can we respond to important demands from the European Commission and from your customers and their associations along the supply chain. Demands such as the FACET initiative where data, for the complete sector, is needed to provide the factual base for future food contact legislation. This will benefit all flexible packaging manufacturers. Neither the 'giants' nor the medium and small manufacturers can achieve this on their own.

> *'All members that contribute will benefit from our strong industry association.'*

The larger companies continue to provide input on both finances and expertise, while the medium-sized, inevitably rising in ranking, will become more visible through their increasing commitment to the industry as a whole.

We are glad to see that members' involvement in our activities is growing. Those who join one of our events or participate in benchmarking or projects for the first time very often take part again; thus proving that there is added value in being an FPE member.

> *'To participate actively means getting the most return on your personal and company contribution to FPE. Our challenge to you is why not increase your efficiency by playing an active role.'*

The more you take part the more you will get back for your company – a stronger FPE together with its expert network will better position flexible packaging interests by rising to the challenges presented by competing packaging materials, legislation and the whole supply chain.

For 2010 our challenges will be to bridge the interests of all our members, regardless of turnover, attract more members and to ensure we all benefit from becoming increasingly involved with the association to the advantage of the flexible packaging industry as a whole.

We count on your continued support and are look forward to hearing from you about what you expect from us.

Stefan Glimm
Executive Director
Flexible Packaging Europe

REACH update

Paul W.Verspoor

Three tiers for Exposure Scenarios

Exposure Scenarios are an important feature of the REACH Registration dossiers. Companies must supply a description, an exposure estimate and, if necessary, Risk Management Measures for every use of a chemical substance, or substances.

Under REACH, the word 'use' is very widely defined; comprising every possible application and handling of the chemical.

Developing Exposure Scenarios is a three tier process, beginning with very wide descriptions and exposure estimates with the help of conservative computer modelling. If the outcome is such that no Risk Management Measures are necessary, the process stops.

If on the other hand exaggerated exposures result, another two steps are possible to reconsider the use in more detail. The second step is again based on more detailed computer modelling, and the third on real exposure data.

To streamline the work on the first tier, a number of 'Use Descriptors' have been developed. The TGD mentions: Sector of use (±25), Chemical product category (40 preparations), Process categories (25), Article categories (±30) and Environmental release categories (22).

European trade associations of down stream users, such as FEICA (adhesive manufacturers), EUPIA (ink makers), Plastics Europe and ESIG (solvent producers) are preparing standard letters for their members to send to all their suppliers. All the common uses of the chemicals in flexible packaging will no doubt be covered in this way.

However, where FPE members use chemicals in niche applications they would be wise not to rely fully on the work of these trade associations. They should communicate their 'niche uses' directly to suppliers. Also where suppliers are not members of an active trade association it may be wise to inform them.

There is a deadline of sorts. For substances with the earliest registration deadline (1 December 2010), down stream users have the right to have their use considered by the manufacturers if they have already provided information on their use before this date.

Considering that supplier trade associations were late in their preparations, member companies should still feel free to communicate after this date. It is advisable, however, not to wait longer than strictly necessary, since the information is needed for the compilation of the registration dossiers.

An FPE guidance document on the subject is available*.

New entries for the Candidate List

An expansion of the existing Candidate List of chemical substances is foreseen. A new list of 15 substances has been 'under consultation' and decisions are expected in the coming months. When these substances are placed in the candidate list it will trigger an obligation to communicate with customers. This is explained in the factsheet *'Candidate List Substances and Communications with Customers'* and can be downloaded from the FPE web site*. Once the new Candidate List is finalised, the list will be communicated to interested FPE members.

Restrictions on Phthalates

The European Commission has asked the European Chemicals Agency (ECHA) to review the available new scientific information for DNOP, DINP, DIDP, DEHP, BBP and DBP. ECHA will evaluate if there is evidence that justifies a re-examination of the existing restrictions.

Registrations by December 1 2010

ECHA expects 9,200 different substances to be registered by the first deadline in December 2010. This is already far more than the originally estimated 3,000. However this seems a rather optimistic estimate, since over 50,000 different substances have been pre-registered in the > 1,000 t/a threshold. ECHA expects that the 9,200 substances will be registered by some 25,000 different companies; less than three legal entities per substance. This seems very low.

Its fall back position is 75,000 (some 8 legal entities per substance); still very low. Currently ECHA is trying to get acquainted with the 'lead-registrants' (the members of a consortium that will actually submit the dossier for a joint submission). So far some 1,650 have declared themselves. Little over a year before the deadline, there are still quite a few missing.

Progress towards registration

The well-established consortia for large volume chemicals seem to be well on their way towards a timely completion of the registration dossiers. But there are still quite a number of substances not covered by 'well established consortia'. Some manufacturers of substances, especially those that are not traditionally recognised to be part of the chemical industry, are only just waking up. They will have trouble getting ready in good time for the deadline.

*www.flexpack-europe.org

News from Brussels

John Dixon

Plastics Directive - 6th Amendment

Regulation (EC) No 975/2009, the 6th Amendment of the Plastics Directive 2002/72/EC, has been published. EFSA has given favourable opinions on a number of monomers and additives.

The Regulation adds these to the Community lists of substances used to manufacture plastic packaging for food contact. This legislation is in the form of a Regulation, not a Directive. It applied from November 9 2009 without having to be enacted in national legislation.

Normally a transition period, e.g. 1 or 2 years, is allowed to permit products to stay on the market while documentation such as Certificates of Compliance can be updated to reflect the new law.

> *This has not been done in this case and representations have been made to the EU Commission to try to correct this.*

Plastics - implementation measure

A more fundamental change in the law relating to Food Contact packaging is being proposed in the Plastics Implementation Measure (PIM). This aims to completely overhaul the Plastics Directive 2002/72.

First it will consolidate 2002/72 and its six subsequent amendments. Second it separates the legal text from the Technical Guidelines, which will appear in a separate document. Beyond this, it wants a broader range of structures and substances within its scope, and to change the conditions for migration testing.

2002/72 applies only to all plastic materials. The PIM recognises that plastics are often coated or printed with inks. In these structures, the plastic components of the coatings and inks will become subject to the same requirements as the plastic layers themselves. Note that any non-plastic components, such as pigments, will not be covered.

Equally, plastic films are often laminated to other non-plastic webs, e.g. paper and aluminium. The plastics layers of such structures will also now have to comply with the compositional requirements of the Regulation. However, if a plastic is separated from the food by a functional barrier, it can be made from unlisted substances provided their migration into the food or simulant can be shown to be less than 10 ppb.

Polymer Production Aids (PPAs) are substances used in the manufacture of polymers which are not intended to have a "technical effect" on the finished product. These PPAs are now brought within the scope of the legislation. There will be a list (incomplete at first) of permitted substances, possibly with restrictions, similar to the lists for monomers and additives. However, other materials used in the polymerisation process, such as catalysts and solvents will not be covered by the Regulation.

PIM proposes a new set of simulants and test conditions to be used for migration testing. It makes a clear distinction between what is needed for Specific Migration tests and the conditions for Overall Migration testing. It introduces the use of modified polyphenylene oxide ("Tenax") as a simulant for specific migration testing of dry foods. For Overall Migration testing, it proposes that the current time and temperature lists are replaced by nine standard conditions.

FPE has been working with bodies such as the Plastics Coordination Group (representing the plastics packaging supply chain) and directly with the Commission, to ensure that the new legislation is workable and does not place unnecessary strain on our industry.

> *Although the latest draft reflects many of FPE's past comments, we have proposed over 50 further changes. These range from the merely editorial – but still vital to ensure that the regulations are unambiguous and easily understood – to the critical, which deal with fundamental matters of principle or practicality.*

Proposals on Nanoparticals

Longer term, we can expect the Commission to introduce proposals for the regulation of nanoparticles in packaging materials. PIM already states that an approval for a substance in a conventional form does not extend to being an approval for it in nanoform. A separate petition to EFSA must be made for such substances.

News from Brussels continued on next page

Substances in the news

FPE's core business is representing the European flexible packaging industry at a European level. This was the reason why in 1998 FPE (under the name Euroflex) was founded. At that time it was discovered that the interests of the European flexible packaging industry were not well guarded. Many issues were at stake – and today even more so! - which require the industry's direct input.

As the fully recognised voice for the European flexible packaging industry, FPE is a constructive partner for the various European institutions (Commission, Parliament, Council of Europe etc.), and FPE liaises with other relevant associations. As such FPE participates in the relevant working groups and committees.

The main goal is to promote and protect the flexible packaging industry in Europe. Therefore FPE is pro-actively involved in all relevant issues, providing adequate information about the European flexible packaging industry to allow authorities to come to realistic and manageable legislation and to prevent misconceptions about the industry.

There is nearly always at least one chemical substance that is receiving what some would see as more than its fair share of publicity. The two which are currently relevant to flexible packaging are: Bisphenol A (BPA) and Melamine.

BPA has come under increasing pressure recently with bans on its presence in food containers for young children either enacted or proposed in Canada and several US States. Bills outlawing it have been tabled in the US Senate and French Parliament. Opponents of the substance quote studies which claim it can act as an endocrine disruptor causing behavioural and reproductive problems as well as being linked to some cancers, obesity and diabetes.

The validity of these studies has been challenged by the chemical industry who quote other studies showing no effects at many times normal human consumption.

Among this wealth of claim and counter claim, it is significant that the German Federal Institute for Risk Assessment (BfR) has concluded that "the normal use of polycarbonate bottles does not lead to a health risk from Bisphenol A for infants and small children".

EFSA has seen no reason to alter its previous 2006 opinion which concluded that exposure is well below the Tolerable Daily Intake (TDI). The US Food and Drug Administration has also declared BPA to be safe, although it is conducting a review due to be published shortly and the US National Institute of Health has also announced a new study into the chemical.

Although much of the discussion has centred on the presence of BPA in polycarbonate feeding bottles for babies and young children, it will also be present in a number of flexible structures, especially those using epoxy coatings. There is a risk that, whatever the Food Safety Authorities say, customers will put suppliers under pressure to supply BPA free alternatives.

In most cases, BPA levels in flexible packaging should be far below the Specific Migration Limit (SML(T) = 0.6mg/kg). Converters would be well advised to be prepared with test results to support their arguments for continued use of BPA in their structures.

Melamine: Following revelations that some Chinese producers of milk powder and pet food had deliberately added melamine to their product in order to improve the apparent levels of protein, questions have been raised as to the level of this substance in packaging materials.

FPE issued a statement last year acknowledging that Melamine based lacquer can be used in flexible packaging, almost always on the non-food contact side of structures. We are now being asked by EFSA for details on where the substance is and is not used. Within the industry, the feeling is that the volume of such structures is relatively low and that the Specific Migration Limit of 30mg/kg is always met comfortably.

Packaging Ink Joint Industry Task Force

FPE representatives are active in many of the committees and working groups that seek to improve food safety and influence the regulations for food contact materials. The Packaging Ink Joint Industry Task Force is one such forum which brings together ink manufacturers, converters and the food industry.

Set up in 2006 following the ITX issue, it has been successful in improving communication along the supply chain. The members of the European Printing Ink Association (EuPIA) now undertake to supply their customers with Statements of Composition on their inks. These should detail the substances listed in the Plastics Directive, Dual Use Substances and other unlisted substances with a molecular weight < 1000 Daltons. They should also include information which will allow the converter to calculate whether there is a danger that any regulatory limits may be exceeded.

Active and Intelligent Materials

Regulation (EC) No 450/2009 on "active and intelligent materials and articles intended to come into contact with food" came into force in June 2009. The rules regarding labelling and declaration of compliance applied from December 2009.

Dossiers on the active and intelligent portions of the pack have to be submitted to the European Food Safety Authority (EFSA) by January 2011 with evidence both that they are effective and that levels of migration to food are not such as to cause consumer harm. Approved substances will be added to a Community List. Note that "released active substances" may be used without being listed, provided they comply with the relevant food regulations. The "passive" parts of the package must still comply with existing food contact regulations.

Research activity

John Dixon

FACET

One of the aims of the FACET project is to be able to improve estimates of consumer exposure to substances like melamine. This will enable a much better application of the Risk Assessment equation: Risk = Hazard (Toxicity) x Occurrence (Exposure)

Currently the exposure is generally greatly overestimated on the basis of a standard 6 dm^2 of packaging per kg food and consumption of 1kg of the food by each consumer each day. Any new evidence of possible toxicity, even at very low concentrations, can immediately cause concern and trigger the "substance of the month" phenomenon.

> *Having a real exposure value will, in many cases, allow us to demonstrate quickly that the risk is low and there is no cause for concern.*

Current legislation focuses on compliance by migration. Flexible packaging, with its wide range of structures, will suffer more than most from regimes that call for more and more extensive testing. However, the main aim for FACET is to enable future regulation to be based on exposure, not migration. This would reduce the need for migration testing of food contact materials and hence reduce our costs. Because of this, FACET is vital to us as an industry.

Equally, flexible packaging accounts for around two-thirds by area of the materials that are in direct contact with food. FPE members supply the majority of that packaging. For FACET to succeed, it needs to know how much of what structures are in contact with which foods. FPE members have that information and will be asked to supply it, on a confidential basis, to a consultant who will collate the figures for input into the project.

> *In summary, FPE needs FACET to succeed; FACET needs the input of FPE members to succeed. So please do all you can to help provide this data.*

Functional barrier

As legislation extends to multi-layer structures and even to multi-material structures, so the term "functional barrier" becomes used more widely.

But what materials provide functional barriers? And to what substances?

To help get some answers to these questions, FPE has commissioned Fraunhofer IVV to carry out a €30,000 research project. FPE members will provide different samples, and migration of defined substances will be studied at a range of temperature conditions.

CONTACT DETAILS

Flexible Packaging Europe
A division of EAFA
Am Bonneshof 5
D- 40474 Düsseldorf
GERMANY

FLEXIBLE PACKAGING EUROPE

Tel+49 211 479 61 50
Fax: +49 211 479 64 08
enquiries@flexpack-europe.org
www.flexpack-europe.org