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Demand for harmonised food contact legislation

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At a time when the United Kingdom is about to take a decision on its future in the EU, it is perhaps worth remembering how much we take for granted that we do business on a truly European level, with little thought of national boundaries. Many of our food customers are pan-European if not pan-global. Even food packers located in just one country frequently export to many more.

Under these circumstances, it is hardly surprising that there is a general wish to have food contact material (FCM) regulation on a European level. National laws can be hard to track down, written in languages that one does not understand, subject to unexpected updates and can even contradict each other. The Framework and GMP Regulations provide a solid harmonised base for FCM but flexible packaging uses many components that lack the specific measures that are in place for plastics. Some 90% of FPE members' products contain one or more such components and hence could be said not to be completely regulated on a European level. In practice, companies are often forced to use the Plastics Regulation to demonstrate the safety of non-plastics such as coatings and inks.

It cannot therefore be resistance from industry than is preventing a fully harmonised FCM regulation. The Commission seems unwilling or unable to move with any speed on the issue. They published a Roadmap in 2012 and last year commissioned a baseline study for the impact assessment requirement. 2017 is probably the very earliest that we could expect to see any proposals.

Instead of concentrating on this key issue, energies seem to be diverted to an even finer tuning of the existing Plastics Regulation. As a result we are seeing the introduction of measures such as an SML for aluminium and a reduction of the SML for zinc, which will do little or nothing to enhance consumer safety but merely place additional testing burdens on the converter.

FPE were given the opportunity to join ACE (The Alliance for Beverage Cartons and the Environment) in writing to DG Sante to express these concerns. You can read the letter by clicking here.

European News

6th Amendment to the Plastics Regulation

Discussions on the 6th Amendment to the Plastics Regulation No. 10/2011 started in April of last year. It now seems that the measure is approaching its final form. Although we still cannot be certain of the content, it is likely to include the following.

SML for Aluminium

Among the most important changes will be a new Specific Migration Limit (SML) of 1 mg/kg food or food simulant for aluminium. People are exposed to aluminium from a variety of sources other than food contact materials (FCM). For example, it occurs naturally in many foodstuffs and it may be used in pharmaceuticals. Hence an allocation factor of 10% was applied to the conventionally derived migration limit. In other words, packaging is allowed to contribute just 10% of the tolerable weekly intake (TWI) which has been established by the European Food Safety Authority (EFSA). This SML is much less than the Specific Release Limit of 5 mg/kg food or food simulant which had been recommended by the Council of Europe. There were many objections to the proposed 1 mg/kg value:

- The existence of two different limits would cause confusion
- In the light of new scientific evidence, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) had raised their TWI from 1 mg per kg body weight per week to 2 mg. The Commission had said that they would ask EFSA to reconsider their TWI but this has never been done.
- The Commission had used exposure considerations when

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applying an allocation factor but had been inconsistent in not considering the consumer exposure to FCM.

- Due to the natural and variable aluminium quantities in foodstuffs, it is not possible to measure concentrations below 4 mg/kg food with any accuracy.

The Commission has chosen to reject – or ignore – these arguments. They claim that the limit only applies to plastics and has no relevance to other food packaging materials such as metals. Sadly, we know that, although this is true in theory, many authorities and customers may apply the lower limit across the board.

SML for Zinc

This will be reduced from 25 mg/kg food or food simulant to 5 mg/kg, also on the basis of an allocation factor for migration from FCM. Zinc containing substances are quite commonly used in plastics but we understand migration levels are generally low and that this new limit is unlikely to be exceeded. At the moment, it is usually possible to demonstrate compliance with the 25 mg/kg limit by a worst case calculation or from an overall migration result. However, the use of these techniques will not be possible with the reduced limit. This will force companies to conduct expensive specific migration tests.

Removal of Generic Specific Migration Limit

Clause 2 of Article 11 lays down a generic SML of 60 mg/kg for all those substances which did not have an individual SML or other restrictions. Under the Plastics Directive 2002/72, the testing conditions for specific migration were the same as for overall migration. Hence the overall migration results could be used to demonstrate compliance with the generic SML. However, the introduction of the Plastics Regulation 10/2011 made overall and specific migration testing conditions different, preventing this approach and potentially forcing companies to carry out a huge new range of burdensome testing. The Commission have responded to the representations of FPE and other associations on this issue; the amendment will remove this clause and hence the generic specific migration limit.

Other Changes

Article 3 will be amended to include a definition of "hot fill" which is likely to be along the lines of "Hot Fill is the filling with food at temperatures not exceeding 100˚C after which the food cools to less than 50˚C within 60 minutes or to less than 30˚C within 150 minutes." This will tie in with amendments to the testing conditions in Annex V which will allow the 10 days at 60˚C test for long term storage at ambient include such hot fill applications.

Some thirteen new substances will be added to the Annex I list of food contact substances and two entries will be amended.

There will be a number of changes in Annexes III and V relating to test simulants and conditions. Many of these are to bring the legal text into line with the 'Technical Guidance for Compliance Testing'. They are too many to discuss in detail but, in general, these changes remove anomalies and uncertainties, making the choice of simulants and test conditions more straightforward.

Guidance

The 'Technical Guidance for Compliance Testing', mentioned above, is still in draft form. Although there are still one or two details being worked on, the main cause of the delay to its publication is the need to amend some of the legal text to tie in with the Guideline. We are therefore unlikely to see it until the 6th Amendment is finalised.

Other European Food Contact Legislation

Bisphenol A (BPA)

The French "suspension" of the use of BPA in FCM has now been operative for over a year. However, in September, the Constitutional Council ruled that the measure unjustifiably restricted trade. As a result, that part of the law which banned the manufacture and export of BPA based FCM to packers outside France has been lifted. The restriction on the use of BPA based FCM inside France remains.

In January 2015, EFSA published their comprehensive re-evaluation of BPA exposure and toxicity. It reduced the TDI from 50 to 4 μg/ kg of body weight per day. Nevertheless, they concluded that, at current exposure levels, BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents).

The Commission seemed slow to respond to this opinion. There were rumours that they might be starting infringement proceedings against France but these remain just rumours. Eventually, in November, they published a "Road Map" which set out a number of options for dealing with the issue. Nothing has yet been decided but it is generally thought that they are favouring a measure which will reduce the SML for BPA in plastics, perhaps to 0.05 mg/kg food (50 ppb), and introduce legislation for BPA in coatings and varnishes, applying a similar migration limit. Other FCM such as papers and adhesives would not be covered by this.

Plastics Recycling Processes

The authorisation of such processes is still occupying much of the Commission's time. They are working on 106 authorisations, mostly for polyester, with two for HDPE and two for closed loop processes. They aim to finalise the work by the summer and have the authorisations in place by autumn.

Biocides

The Commission have stated that the introduction of legislation for the use of biocides in food contact materials is a priority. They produced a preliminary proposal in early 2014. However, active biocidal substances must be approved by ECHA and food contact substances must be evaluated by EFSA. It would appear that there are considerable difficulties in getting both these processes to proceed in tandem and this has so far prevented any further progress.

Non Harmonised Materials

In 2012, the Commission published their Road Map for legislation on non-harmonised FCM – that is for almost all materials other than

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plastics. Last year, the Joint Research Centre started work on a "baseline study". This will record the existing national measures and estimate their associated costs. FPE have contributed to this work.

It is not clear when the next step will be taken. Meanwhile, the calls from industry and environmental groups for the Commission to introduce legislation get louder and louder. The European Parliament's Committee on Environment, Public Health and Food Safety recently held a Workshop which is expected to result in a report which will demand harmonised measures. In response, the Commission have said that they will listen to proposals but also have suggested that it would perhaps be better to strengthen the mutual recognition principle.

Cosmetics **Packaging**

In order to assess the safety of the packaging used for their products, cosmetics companies require information from their packaging suppliers. Over the last couple of years, representatives of the cosmetics and packaging industries have been meeting in a task force to try to develop a practical method for doing this. This has now resulted in the publication of 'Packaging Information Exchange Guidelines'.

Most flexible materials that are used for cosmetics are also used for packing food. These Guidelines allow a food contact status to be used as a basis for the cosmetics company's safety assessment. They include a template "Regulatory Information File" for transfer of the necessary information along the packaging supply chain. However, the requirements of the Cosmetics Regulation are such that there are over 3,000 substances "of concern" for which the assessor needs specific information on whether they are present or not. These include skin sensitisers and substances with a Carcinogenic, Mutagenic or Reprotoxic (CMR) classification or with a listing in Annexes I and II of the Cosmetics Regulation.

There are practical difficulties for packaging manufacturers to get assurances from their suppliers that none of these 3,000 substances are present in their materials. Therefore, the task force researched which of these substances might reasonably expected to be present in FCM, resulting in a shorter "Guidance List of Disclosable Substances". This reduces the 3,000 substances to 176, a more manageable list for use within the packaging supply chain.

These guidelines will operate on a trial basis for the next six months. FPE members are encouraged to use them and report back their experiences – good and bad – so that any necessary improvements can be made.

REACH

Restriction on **Isocyanates**

The majority of flexible packaging laminates are made using curing polyurethane adhesives. Before curing, such adhesives generally contain residual amounts of diisocyanate monomers. Germany is now preparing a dossier for a Restriction for such mixtures. The text has not yet been finalised but it might say that diisocyanates cannot be used unless:

a) Their concentration in the mixture is less than 0.1% by weight. The isocyanate component of the adhesive as received will usually have a concentration greater than this; however, when the adhesive is mixed, the concentration may fall below the limit and so the Restriction will no longer apply.
b) Measurements under realistic conditions have demonstrated that only an acceptable residual risk is present. These uses will be recorded as "Exemptions" in Appendix M.
c) The mixture is used in accordance with certain provisions, listed in Appendix N. In practice, this means that the company will have to demonstrate that the workforce have been appropriately trained in the safe use of isocyanates in accordance with certified schemes.

For the flexible packaging converter, the main impact of this Restriction will be the need to train their workforce in accordance with an approved scheme. Actual working practices, provided they are already safe, are unlikely to be affected.

Chromium **VI**

Within REACH, there is the possibility of making a substance subject to Authorisation. Chromium VI is currently in the process of being added to the Annex XIV list, after which it can no longer be used except for those applications for which it has been specifically authorised. The use of the substance is held to be essential in the manufacture of gravure printing cylinders and the European Rotogravure Association, representing the cylinder makers, is part of a consortium seeking Authorisation for such functional coating applications.

The application is now being considered by the EU Risk Assessment and the EU Socio Economic Assessment Committees. Publication of their recommendations is expected in the first half of this year. The final decision of the EU Commission will follow ten months later. Members are advised to keep in close touch with their cylinder suppliers on this issue.

Sustances of **Very High Concern (SVHC) in Articles**

The REACH Regulation provides that, where an SVHC is present in an article at more than 0.1% by weight, the producer or importer must notify the European Chemicals Agency (ECHA). Similarly, the

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supplier must inform the recipient of the article and, on request, the consumer. ECHA had held that the weight of the whole article should be used when calculating the 0.1%.

Five Member States disagreed, holding that, for an article which is itself made up of two or more components which are themselves articles, the duty to notify and provide information continues to apply to **each** component which contains an SVHC at more than 0.1% of the weight of the **individual** component. In September last year, the European Court of Justice upheld this challenge.So far as flexibles are concerned this means that:

- If you have an ink, coating or an adhesive (i.e. a mixture) which contains more than 0.1% SVHC and apply it to a substrate without a chemical reaction (i.e. the SVHC remains), then the percentage of SVHC should be calculated on the weight of the entire finished article. The reason is that the SVHC was originally contained in a mixture not an article. The dried ink, coating or an adhesive has not become an individual article because it cannot exist on its own.
- If the ink, coating or an adhesive reacts so that the SVHC is consumed during the production process (e.g. by the curing of an adhesive or coating), then the calculation should be based on the weight that remains, not the starting level.
- If you combined two articles in a reversible way, e.g. a self-adhesive label with a backing release web, and one of those articles contained more than 0.1% SVHC, then you would then have an obligation to declare its presence even if the concentration in the final combined product fell below 0.1%.

However, there is less clarity on the scenario of combining two or more articles in a more permanent way, e.g. by adhesive laminating two films, and where one of those articles contained > 0.1% SVHC. We are seeking guidance on this issue.

BREF

BREF Revision

The process to update the Best Available Techniques Reference Document (BREF) for "Surface Treatment Using Organic Solvents" is well under way. The Technical Working Group held its "kick-off" meeting in November. Key actions over the coming months are the preparation of questionnaires to collect data on current emission levels and the identification of representative sites to answer these questionnaires. This data collection is scheduled to be completed by the middle of this year. FPE's consultant for this activity, Rudi Brenk, is being supported by a "Shadow Group" of five of our larger members plus a representative from Giflex.

National News

Swiss Ordinance

Last year, the Swiss announced that, as part of a general revision of their Ordinance on Materials and Articles (in contact with food), there would be a 5th revision of annex 6 which lists the substances used for the manufacture of packaging inks. A number of List B (unevaluated) substances have a CMR classification and these would be removed unless a dossier were submitted allowing them to be evaluated and placed in List A.

German Ordinance

After producing a new draft of their ink regulation in early 2015, there was silence on the issue until the very end of the year when we heard that a new draft would be notified to the Commission in the near future. So far, we have not heard of such a notification nor have we seen a copy of the new draft.

Even if it were notified in the near future, the legislation would not be completed until early 2017, with a two year transition period taking full implementation to early 2019.

Other National Legislation

At the start of 2015, there was an exchange of letters between the Commission and the Belgian authorities on the proposed Royal Decree on varnishes and coatings intended to come into contact with food. Since then, nothing has been heard. Similarly, there do not appear to have been any further developments on the proposed German regulation on mineral oils.

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