EuPIA Interview

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What is the PIFOOD committee and what is its role?

PIFOOD is an acronym for Printing Inks for Food Packaging. The formulation and production of printing inks for food packaging requires special knowledge, carefully selected raw materials, and needs to be conducted in compliance with Good Manufacturing Practice (GMP). Although packaging inks are not yet covered by a specific harmonised regulation in Europe, printed products must be safe for the consumer and comply with Article 3 of the Framework Regulation for food contact materials. Finally, this legislation stipulates that it is the responsibility of the supplier of the final printed packaging to demonstrate compliance. However, as ink suppliers, we have a major role to play in enabling this compliance. The role of the PIFOOD committee is to watch the development of food contact material legislation on a national and European level and develop industry guidelines to support printing ink manufacturers and converters to make sure that their products can be safely used for the intended applications. Also, PIFOOD gives guidance as to which information must be shared along the supply chain to arrive at a packed product that consumers can safely use.

Who sits on the PIFOOD committee?

On the PIFOOD technical committee, we have regulatory and ink experts from affected EuPIA member companies. Usually, we meet twice per year and our meetings typically consist of about 50 experts from more than 30 companies discussing what we need to do as an industry to fulfill our legal obligations. In order to coordinate the work in the PIFOOD committee and to work on specific projects between the plenary meetings, we have smaller working groups, as well as the PIFOOD VISION group, in which we pre-discuss key strategic topics.

What are the notable projects and initiatives the PIFOOD committee has historically worked on?

One of the key requirements of the Framework Regulations for food contact materials is that these products need to be produced under Good Manufacturing Practice (GMP). In 2016, we created a detailed EuPIA GMP Guideline, which explains how the requirements need to be translated into ink

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formulation and production. For example, we created a Raw Material Questionnaire that can be used by EuPIA members to secure key data from raw material suppliers to ensure that in printing inks for food packaging applications only suitable substances are used. Furthermore, ink manufacturers need to make sure that the information is properly passed to customers in the supply chain so they can play their part in the compliance work.

Today, the "Statement of Composition" contains the relevant information for our customers and has developed into a very well accepted standard in our industry. In addition, in order to improve the Risk Assessment, we developed our "EuPIA Guidance for Non-intentionally Added (NIAS) and Non-listed Substances (NLS)" and the "EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials." These are just some of the important documents that have been developed by this committee. I invite everyone to check the website www.EuPIA.org where many other documents can also be found.

What is the status of the proposed harmonised EU legislation on printing inks for food contact materials (FCM)?

Driven by the German Initiative for a National Ink Ordinance the European Commission announced at the close of 2016 its intention to begin working on a printed food contact material legislation (p-FCM), which was originally planned to come into force in 2018. However, it was later decided, as a first step, to evaluate the European Framework Regulation for Food Contact Materials. This basic piece of legislation is now more than 40 years old and the Commission wanted to see whether it needs to be modified to be fit for the future.

There have been many meetings and stakeholder discussions to date and PIFOOD experts participate in these discussions. In September, we received the final consultant's report who completed the evaluation study. We are now carefully reviewing this report and are in discussions with all members of the food packaging material supply chain (PIJITF*). In principle, the study confirms that the Framework Regulation contributes to the safety of food contact materials, but the report also identifies some points in which it may require some updates. For example, currently we have an up-to-date legislation in Europe pertaining to all chemicals used in the EU market (REACH). The data which has been created via that process could be used to improve the safety of food contact materials. Additionally, the Risk Assessment principles that have been developed over the past 40 years now also include modern in-vitro (test in cell cultures outside a living animal) and even in-silico tools (calculation models in computer software), used to evaluate the hazard potential of substances. These tools could contribute significantly, for example to reduce animal testing, without compromising on results related to food safety. EuPIA PIFOOD is working in this direction and is trying to get these modern tools implemented in the future p-FCM legislation.

EuPIA and the entire food packaging chain continue to advocate for a pFCM measure to be developed as soon as possible. Until such time, we continue as an industry to use our guidelines and measures to ensure that substances used in printing inks do not cause a risk to the health of the consumer.

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Which tools is the ink industry using, in the absence of an EU ink regulation, in order to make sure that pFCM can be compliant with the Regulation (EC) 1935 (2004)?

We have laid down our principles for Risk Assessment in detail in our "EuPIA Guidance for Non-intentionally Added (NIAS) and Non-listed Substances (NLS)".

Substances which are used to produce printing inks for food contact materials must be risk assessed. This requires, as a first step, to identify which substances are present and here we work closely together with our suppliers.

For the risk assessment we then use a tiered approach:

When ingredients are identified, we check if these substances have been part of an official toxicological evaluation; for example, by EFSA or national authorities. If this is the case, then the relevant migration limits are used.

If this is not the case, then we check if we can find any public toxicological studies. The data collected during the REACH process is very helpful and we also use the published data in the ECHA database. This data typically includes studies on genotoxicity and oral consumption data. If the data is available and reliable, it may be used to derive a migration limit for the substance. In some cases, such toxicological data is not available, in which case we use the concept of "Threshold of Toxicological Concern" (TTC). This concept groups chemical substances by various criteria into categories, called Cramer Classes. Each Cramer Class is associated with a migration limit; if a substance can be grouped into one of the 3 groups, we use the relevant limit.

One problem with the TTC approach is that it cannot be used for some substance groups and moreover, it must be demonstrated that the substance is not genotoxic. The problem with genotoxic substances is that even one molecule could in principle damage human DNA and cause cancer. Therefore, we need tools to demonstrate that a substance is not genotoxic. This can be done by in-silico tools such as (Q)SAR. In simple words, these (Q)SAR computer programs are analysing the structure of a molecule and comparing it with a set of similar substances for which the toxicological profile is known. Based on this comparison, the risk of genotoxicity, or not, can be predicted. EuPIA PIFOOD has already organised two training sessions for our members and we are planning another one in December.

What is the Packaging Joint Industry Task Force (PIJITF) and the Cross-Sector Group and how does EuPIA cooperate with them?

The Packaging Joint Industry Task Force (PIJITF) was created many years ago when there was a specific case where baby milk products were contaminated with the photoinitiator ITX from UV flexo printed packaging.

In PIJITF, the complete food packaging supply chain is represented, starting from raw material suppliers, formulators (inks & adhesives), substrate producers (plastic films & paper), printers, and also the food industry. Within this group, we discuss what is needed from each level of the value chain to ensure that the final packed food product placed on shelves in a supermarket can be safely used by the consumer. We aim to make sure that we all work in the same and right direction and follow the same basic principles. The safety of food packaging must

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be always a joint approach and cannot be secured by only one partner in the supply chain.

The Cross-Sector Group (CSG) is even one level higher. The Framework Regulations on food contact materials defines 17 material groups for which individual harmonised measures can be made. This includes, for example, plastic, paper, inks and adhesives – and also wood, enamel and metal. In the Cross-Sector Group, we have representatives of many food contact material manufacturers, from the chemical industry up to the producers of household goods like coffee machines. The goal of the CSG is to develop basic principles which need to be considered by all players in any food contact material related sector.

What bottleneck does the ink industry see for a future legislation and do we have ideas how this can be solved?

First of all, it is important to mention that even if we have no harmonised legislation for inks and most food contact material groups in the EU Framework Regulations, these articles are safe for the consumer. The industry takes measures day-by-day to ensure that printed food packaging materials are safe.

Secondly, the printing ink industry wants a harmonised legislation and no national patchwork of regulations. We are an international, organised industry and need free access to the market. Any national regulations can become a significant barrier for market access. Finally, we believe that the industry must have a major place in the development of future legislation on how to assess the risk that is related to substances used in p-FCMs. As an example, the Swiss Ordinance on printing inks used in food contact materials lists more than 5000 substances. Only a bit more than 1000 have been officially evaluated by EFSA or national authorities. In order to complete the evaluation of the remaining 4000 substances with the current approach would take decades – this is simply not realistic or feasible. However, these substances are already in use today and there is no risk with today's packaging materials. Therefore, why not officially recognise the methods that are used today by the printing industry based on EuPIA principles and guidelines? Of course, these methods and guidelines are under constant review, and if we have better methods we will always adopt them.

The members of EuPIA PIFOOD have over many years developed industry guidelines, which ensure that printing inks which are offered for food packaging applications can be used safely and without any risk for the consumer. These guidelines are constantly updated and adapted to new scientific data or changes in legislation. We also work closely together with all other partners in the food supply chain, as we all want to ensure that the material which is used to pack food is always fit for the intended purpose and can be used safely.

* PIJITF= Packaging Ink Joint Industry Task Force, represents the members of the food packaging supply chain that are concerned with the application of printing inks onto food contact materials and their subsequent use

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