Frequently Asked Questions
ON THE LEGAL STATUS OF PRINTING INKS, COATINGS AND VARNISHES FOR FOOD CONTACT MATERIALS (FCM INKS)

1. **Does EU legislation on printing inks for food contact materials exist?**
   Up to now, no specific EU harmonised legislation on printing inks for food contact materials (FCM inks) has been issued, with the exception of Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film, which states that the printed surface of regenerated cellulose film must not come into contact with food, and therefore is relevant to printing inks for food contact materials.

2. **Are printing inks subject to any other EU legislation?**
   Even if printing inks are applied on the non-food contact surface of food contact materials (FCM), as a component of the printed FCM, they must not prevent the final FCM from meeting the requirements of Regulation (EC) No 1935/2004 concerning materials and articles intended to come into contact with foodstuffs.

   This Regulation requires that no food contact material (whether printed or not) should endanger human health, change the composition of the food or alter the organoleptic properties of the food. This Regulation repealed Framework Directive 89/109/EEC and, as a Regulation, immediately came into force in the Member States on 3 December 2004.

   In addition, Commission Regulation (EC) No 2023/2006 “on good manufacturing practice for materials and articles intended to come into contact with food” also makes specific reference to printing inks.

3. **Are printing inks covered by other provisions?**
   In 2005, the Council of Europe (CoE) Committee of Ministers of the Partial Agreement in the Social and Public Health Field adopted the Resolution ResAP (2005)2 on “Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging”. CoE Resolutions are not legally binding, but should be considered as statements of policy for national policy makers of the Partial Agreement member states. EuPIA could not support the Resolution as adopted, because it was not practicable. The substance inventory lists were not sufficiently comprehensive, and did not provide protection for consumer health or reflect current practices.

   Up to now, Switzerland is the only member state of the CoE Partial Agreement who decided to translate the Resolution ResAP (2005)2 into its national legislation. In 2008 an amendment to the Swiss Ordinance on Materials and Articles (SR 817.023.21) was made, detailing certain provisions specific to FCM inks applied on the non-food contact surface of FCMs. The core element of the new regulation is a list of “permitted substances”, identifying the only substances which may be used in the manufacture of those inks marketed in Switzerland. This list, which has been established with the support of EuPIA and CEFIC, became applicable as from 1st April 2010. Following the revision of the lists in 2011, another update was made in 2016. As part of this revision, the two lists A and B of Annex 6 have been combined. The new version now contains the positive list as Annex 10 in a revised form. The amended regulation entered into force in May 2017. A transition period of four years applies, which does not only relate to compositional requirements, labelling and advertising, but also to the specific migration limits. This means that SMLs as specified in Annex 10 are legally enforceable from 30th April 2021; therefore, the SMLs

as laid down in Annex 6 (4th edition,1st December 2012) are legally applicable until this date. For more information on the Swiss Ordinance please consult the relevant EuPIA Q&A document.

In the absence of specific EU legislation, EuPIA issued a "Good Manufacturing Practice (GMP) for Printing Inks for Food Contact Materials" (4th completely revised version, March 2016) setting out a mechanism for the selection of raw materials for FCM inks. It is considered that this GMP satisfies the current requirements of the food contact material chain.

4. **What is the industry position on positive lists for FCM inks raw materials?**
   As part of an integrated approach to risk assessment positive lists may help in communicating developed toxicological data and harmonized migration limits. They provide transparency for substances used, however any positive list alone does not guarantee pack safety.

5. **What is the industry position on non-evaluated substances used in FCM inks?**
   To cover all market technical demands, non-evaluated substances are often required. This does not pose a problem as long as the relevant migration threshold of the substance from the printed FCM into the foodstuff is met.

6. **What is the industry position on threshold limits of substances migrating from the dried printing ink layer?**
   Where they exist, specific migration limits (SML) must be met. With regard to non-evaluated substances, migration limits of no concern - based on toxicological assessments – have to be established.

7. **Are there any special issues related to the use of energy curing printing inks for food contact materials?**
   EuPIA members can confirm that, as with other ink types, UV curable materials can be used safely for food packages providing that the conditions of the EuPIA GMP are met, as with all FCM inks.

8. **What are the legal responsibilities in the food contact material chain?**
   Due to the complexity of the process, all members of the food contact material chain must exchange relevant information – under appropriate confidentiality agreements if necessary – in order to ensure that products can be formulated to be fit for purpose, and thus be compliant with all legal responsibilities. To this end EuPIA members will provide adequate information about the composition of their products by means of a standard Statement of Composition. This will allow the manufacturer of the printed food contact material and the food filler to meet their legal responsibility to ensure that it is fit for its intended purpose.

   There are many types of final package and the printing ink is only one constituent. Since the parameters in the printing, packing and storage processes are not under the control of the printing ink manufacturer, the printing ink suppliers are not able to issue certificates or declarations of compliance which cover the legal responsibility of the entire food contact material chain.

9. **How are the responsibilities in the food contact material chain managed?**
   According to Good Manufacturing Practices, or quality control standards, the co-operation between all members of the food contact material chain is managed by requirement specifications, e.g. by information about the substrates, type of food packed, printing and converting process parameters, storage and treatment conditions. The ink manufacturer will

formulate the ink accordingly, which if used correctly will allow the final FCM to meet the legal requirements.

10. **What information will member companies of EuPIA make available on FCM inks to enable the rest of the food contact material chain to meet the legal requirements?**
    EuPIA members will identify which specific components in the FCM inks offered by them should be monitored to assess compliance. They will make available such information to those parties specifically involved in the compliance control. To this end they are prepared to provide a Statement of Composition.

11. **What specific verifications of compliance are recommended to users of FCM ink products?**
    The printer should conduct representative practical investigations, such as migration testing or migration modelling, to cover each relevant FCM application category and structure.
    If required, EuPIA members can help identify suitable laboratories that have the required analytical capability to give a qualified verification of compliance of printed FCMs.

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